PB91-130187

Medical Waste Management in the United States
Second Interim Report to Congress

(U.S.) Environmental Protection Agency, Washington, DC

Dec 90

U.S. Department of Commerce
National Technical Information Service
NTIS

PB91-130187

United States
Environmental Protection
Agency

Solid Waste and
Emergency Response
(OS-305)

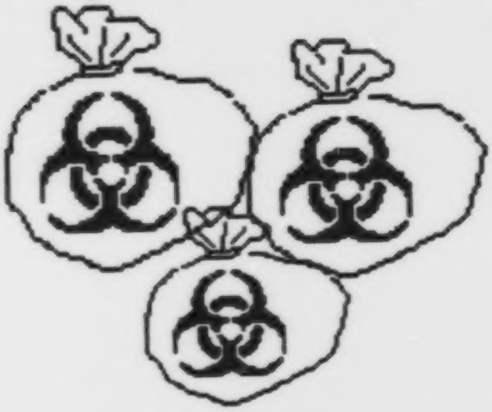
EPA/530-SW-90-087A
December 1990

Office of Solid Waste

EPA

Medical Waste Management in the United States

Second Interim Report to Congress



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NATIONAL TECHNICAL
INFORMATION SERVICE
SPRINGFIELD, VA 22161

50272-101

REPORT DOCUMENTATION PAGE

1. REPORT NO.
EPA/530-SW-91-087A

2.

3.
PB91-130187

4. Title and Subtitle
MEDICAL WASTE MANAGEMENT IN THE UNITED STATES (SECOND INTERIM REPORT TO CONGRESS)

5. Report Date
DECEMBER 1990

6.

7. Author(s)

OFFICE OF SOLID WASTE

8. Performing Organization Rept. No

9. Performing Organization Name and Address

U.S. EPA
Office of Solid Waste
401 M. Street SW
Washington, DC 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.
(C)
(G)

12. Sponsoring Organization Name and Address

13. Type of Report & Period Covered
REPORT TO CONGRESS 12/90

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

The SEcond Reprot is divided into 5 sections, each of which addresses the MWTA and EPA's medical waste program from a slightly different perspectie. Section I briefly explains the purpose and content; Section II reviews the key issues that led to the passage of the MWTA (Medical Waste Tracking Act); Section III consists of a detailed analysis of EPA's evolving medical waste program; Section IV discusses the impact of the program; and Section V concludes with a research update and forecast.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement
RELEASE UNLIMITED

19. Security Class (This Report)
UNCLASSIFIED

20. Security Class (This Page)
UNCLASSIFIED

21. No. of Pages
160

22. Price

(See ANSI-Z39.18)

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)

EPA/530-SW-90-087A

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Medical Waste Management in the United States

December 1990

United States Environmental Protection Agency
Office of Solid Waste

MEDICAL WASTE MANAGEMENT IN THE UNITED STATES

Second Interim Report to Congress
Pursuant to the
Medical Waste Tracking Act of 1988

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EXECUTIVE SUMMARY

Since the Medical Waste Tracking Act was enacted in the fall of 1988, EPA has developed a coordinated, multi-component program to address concerns about medical waste management, and the lack of information on the subject. This report -- the second of three reports that EPA is required to prepare under the Act -- describes each of the components in the program, discusses the impacts of the program, and provides an update on the status of research activities that have been initiated for each of the 12 subject areas identified in the Act.

EPA's medical waste program is comprised of five integrated components. Briefly, they are:

- a tracking system designed to ensure that medical waste transported off-site reaches its destination;
- a management program designed to ensure that waste is properly segregated, packaged, marked, labelled and stored prior to transport;
- information gathering, research, and analysis to fill data gaps, evaluate the results of Agency actions, and enable informed debate concerning the future of Federal medical waste regulation;
- an education, outreach and training program targeted at both the regulated and unregulated communities, including Federal and State officials charged with implementing the program, other Federal agencies involved with medical waste (e.g., OSHA) and the home health care sector; and
- an enforcement strategy designed to maximize innovative enforcement by the covered States, encourage the regulated community to comply with the program and deter and punish noncompliance.

The regulatory components of the program terminate at the end of the demonstration program in June of 1991. The other components of the program, such as outreach to the home health care sector, however, may continue indefinitely.

Although the Agency believes that it is premature to evaluate the success of the program that has been in place approximately a year, it has identified a number of direct and indirect effects on the management, handling, and disposal of medical waste resulting from the program. The most significant results include the development of a regulatory program that includes standards for tracking and managing medical waste, and expanding the state of knowledge in several areas related to medical waste generation, management, and disposal. The program has also had several indirect effects, including the encouragement of innovation in treatment technologies, the reevaluation of home health care waste management, some likely reduction in the severity of beach wash-ups, and the contribution to program development in noncovered States.

In the first interim report, EPA summarized information that was then available, and outlined an agenda for additional research on each of 12 specific areas regarding medical waste that were identified in the Act. This second interim report provides a research update and forecast on each of those subject areas. Since the first report, EPA has made substantial progress in several areas, including characterization of the generation and management of medical waste, and development of guidelines for home health care waste. Additionally, several studies are currently underway which will contribute greatly to the understanding of treatment technologies, and the risks associated with the medical waste.

I: BACKGROUND AND INTRODUCTION

A. Background

This report was prepared pursuant to the Medical Waste Tracking Act of 1988, Public Law 100-582, codified at 42 U.S.C. §§ 6992-6992k (the MWTA or the Act). The MWTA requires the United States Environmental Protection Agency (EPA or the Agency) to submit to Congress three reports evaluating EPA's medical waste program and other medical waste issues listed in the Act. The First Interim Report to Congress has been submitted; this report is the Second Interim Report.

The Act states that this Second Interim Report shall be due 12 months after the effective date of the regulations -- which became effective on June 22, 1989 -- and shall (like the First Interim Report) cover 12 topics listed in the Act, based on the information available at the time the Report is submitted.[1]

B. Introduction to the Second Interim Report

The First Interim Report is divided into twelve chapters that strictly correspond to the topics listed in the MWTA. It reviews the information available at this early stage of the development of the medical waste program and sets out EPA's initial research agenda and data collection efforts.

This Second Report is written in a somewhat different format. It is divided into five sections, each of which addresses the MWTA and EPA's medical waste program from a slightly different perspective. Section I briefly explains the purpose and content of this Second Interim Report. Section II reviews the key issues that led to the passage of the MWTA, emphasizing the Congressional concerns that have shaped the Agency's development of its medical waste program. Section III consists of a detailed analysis of EPA's evolving medical waste program. It discusses how EPA is building its medical waste program to encompass the MWTA and the interim final rules[2], as well as to address other issues that concerned Congress. In Section IV the Report discusses the impact of the program -- its direct and indirect effects on the handling, disposal and management of medical waste -- and sets out the significant issues that will influence the future of the program. Finally, Section V of the Report concludes with a research update and forecast. The update discusses individually each of the twelve chapters from the First Interim Report, describing the progress in each area since the publication of the First Interim Report and the Agency's future efforts with respect to each research area.

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[1] See 42 U.S.C. §6992g (b).

[2] The interim final rules of the medical waste program were published in the Federal Register on March 24, 1989 (54 Fed. Reg. 12326-95) and are codified at 40 C.F.R. Part 259.

The final report, due in September, 1991, will more completely address the issues raised in this Report and the First Interim Report. In the final report, the Agency also will provide information on the effectiveness of the program and make recommendations on whether a continuing program is needed, and if so, on the components that such a program should include.

II: EVOLUTION OF THE AGENCY'S MEDICAL WASTE PROGRAM

This Report begins with a discussion of the various concerns that led Congress to pass the Act in the fall of 1988. The discussion highlights those aspects of the Act and its legislative history that shaped the Agency's development of the medical waste program. The rapid promulgation of the interim final rules, the speedy development of the enforcement strategy, the prompt commencement of information gathering and data collection, and the continuing efforts at outreach and education that are described more fully in this Report reflect the seriousness with which the Agency has confronted medical waste and its recognition of Congressional concerns about medical waste.

The MWTA was enacted as a response to public concern over the degradation of shoreline areas from wash-ups of sewage and floating debris, some of which was medical waste. The debris raising the most concern were medical wastes such as needles, syringes, blood bags, bandages, and vials. See 134 Cong. Rec. S 10737 (daily ed. August 3, 1988). The result of the beach wash-ups was the closure of beaches, economic losses in affected shore communities, and public concern over the health hazards associated with medical wastes, particularly syringes, and the general degradation of the vulnerable shore environment. 134 Cong. Rec. S 19745 (daily ed. August 4, 1988) and 134 Cong. Rec. H 9536 (daily ed. October 4, 1988).

There were also reports of other incidents of careless management of medical waste; for instance, by disposal into open dumpsters, creating additional concern for public safety. 134 Cong. Rec. H 9536 (daily ed. October 4, 1988). Concern regarding occupational risks to waste handlers arose for similar reasons. Congress was mindful of the environmental issues associated with the medical waste disposal practices. For example, medical waste contains a relatively high amount of plastics, and is commonly incinerated at facilities located in population centers. Moreover, testimony at Congressional hearings questioned whether hospital incinerators as a general rule were well operated or meeting established pollution standards. Congress also recognized that landfill operators were reluctant to accept medical waste, and many States and municipalities were enacting laws prohibiting the landfilling of medical waste. As the options for legally and economically disposing of medical waste diminished, problems associated with shipping medical waste increased, as did the risk of illegal dumping.[3]

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[3] The Congressional concerns discussed here are set forth in the various hearings, and the discussions contained therein, that were held regarding the medical waste problem. See generally, Health Hazards Posed in the Generation, Handling, and Disposal of Infectious Wastes: Hearing Before the Subcommittee on Regulation and Business Opportunities of the House Committee on Small Business, 100th Cong., 2d Sess. (1988); Medical Waste and Sewage Contamination: Hearing Before the Subcommittee on Fisheries and Wildlife Conservation of the Environment of the Committee on Merchant Marine and Fisheries, 100th Cong. 2d Sess. (1988).

Congress was also aware of the patchwork of State and local laws regarding medical waste; medical waste was often unregulated or partially regulated. It discovered that not all States or localities had medical waste programs. Thus, many States and municipalities were not in a position to address the problem adequately. Even among States and municipalities that had adopted medical waste management programs in the wake of the beach wash-ups and closings, the scope, intent and effectiveness of the programs varied widely. In addition, because of the jurisdictional restrictions on their authority, States and localities could not address the interstate nature of the medical waste problem. Thus, medical waste generators sometimes could "forum shop" to avoid State and municipal disposal regulations by shipping waste to a State or locality without a medical waste program. Also, State legislatures and local bodies potentially were vulnerable to influence from the local regulated community.

The MWTA was enacted against this background of health and environmental concerns and was intended to be a first step in addressing these concerns. 134 Cong. Rec. S 15327 (daily ed. October 7, 1988). The Act required EPA to establish a two-year demonstration program that addresses the medical waste management problem in several ways. First, the demonstration program establishes a tracking system that is designed to be implemented quickly so that, to the extent the program controls sources contributing to wash-ups, wash-ups of medical waste in the future will be minimized. Id. Second, the tracking, labelling, packaging and storage requirements are designed to prevent careless management of the waste and to subject violators to administrative, civil, and criminal penalties. 134 Cong. Rec S 15328 (daily ed. October 7, 1988). Third, the tracking system assures that a shipment of medical waste, in fact, reaches its intended destination, and provides a mechanism for tracing incidents of improper disposal to responsible parties. 134 Cong. Rec. H 9537 (daily ed. October 4, 1988) and 134 Cong. Rec. S 10745 (daily ed. August 3, 1988). Finally, the Act requires EPA to provide information to Congress on several subjects, including the effectiveness of the program and whether and how a broader program should be developed. 134 Cong Rec. S 10743 (daily ed. August 3, 1988).

Under the MWTA, EPA has developed a program that includes not only the demonstration tracking and management program prescribed by the Act but addresses other Congressional concerns as well. The next section will describe and evaluate EPA's medical waste program on a component-by-component basis.

III. THE MEDICAL WASTE PROGRAM

A. Overview of EPA's Medical Waste Program

The complexity of the concerns and issues associated with the management of medical waste has led EPA to create a multifaceted, broad-ranging medical waste program. This program consists of five integrated components which have ordered and shaped the activities undertaken by EPA. Briefly, they are:

- a tracking system designed to ensure that medical waste transported off-site reaches its destination;
- a management program designed to ensure that waste is properly segregated, packaged, marked, labelled and stored prior to transport;
- information gathering, research, and analysis to fill data gaps, evaluate the results of Agency actions, and enable informed debate concerning the future of Federal medical waste regulation;
- an education, outreach and training program targeted at both the regulated and unregulated communities, including Federal and State officials charged with implementing the program, other Federal agencies involved with medical waste (e.g., OSHA) and the home health care sector; and
- an enforcement strategy designed to maximize innovative enforcement by the covered States, encourage the regulated community to comply with the program and deter and punish noncompliance.

In order to implement its program, the Agency has promulgated interim final rules,[4] developed an enforcement strategy, initiated procedures to collect and analyze data, and prepared and disseminated educational and instructional materials. The following detailed discussion of these program components highlights the broad scope of the Agency's medical waste program.

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[4] The interim final rules became effective in June, 1989 in New York, New Jersey and Connecticut. The rules became effective in Rhode Island and Puerto Rico in July, 1989. The States participating in the program--New York, Connecticut, Rhode Island and New Jersey--and the Commonwealth of Puerto Rico are referred to collectively as the "covered" States. All other States are referred to as "noncovered" States.

B. The Medical Waste Program -- A Description of Program Components

1. The Tracking System

As its name implies, the core of the MWTA consists of the requirement that medical waste shipped off-site is tracked to its destination. The tracking system is based upon the well-established hazardous waste manifest system. The key to the system is the medical waste tracking form. The form, initiated by the waste generator or transporter[5], stays with the waste until it reaches its final destination. From the time the tracking form is initiated until it reaches its final destination (or until the waste is both treated and destroyed) all waste handlers must complete their portion of the form.

To bolster the effectiveness and integrity of the tracking system, the generator, transporter and treatment, destruction, and disposal (TDD) facility have added responsibilities. The generator (or the transporter, if he initiates the manifest) is responsible for determining the status of the waste shipment if he does not receive a completed tracking form from the TDD facility. If the generator cannot resolve the problem by locating the waste shipment, he must notify EPA and the State where he is located, in writing, that the waste did not arrive at its intended destination. This written declaration is referred to as an "exception report."

In order to transport medical waste, the transporter must notify EPA and the covered State in writing (on an EPA designed form) that he is transporting medical waste. The notification form requires each transporter to certify, under penalty of criminal and/or civil prosecution, that he will comply with the medical waste rules promulgated by EPA. EPA has assigned identification numbers to transporters.

Every TDD facility is required by rule to check and verify the forms against the shipments of medical waste, attempt to resolve any discrepancies, and send a letter to EPA and the States where the waste was generated and disposed if discrepancies cannot be resolved. These letters are referred to as "discrepancy reports."

By identifying all handlers of each shipment of regulated medical waste as well as its generator and final destination, by requiring that the form follows the waste, and by mandating exception and discrepancy reports, the tracking system constructs a "closed circle" that facilitates proper management, encourages proper disposal and reveals potential waste mismanagement. Exception and discrepancy reports, and other reporting requirements of the program, also provide a cost-effective way to pinpoint potential violations and provide the Agency with invaluable data about the nature of the regulated community and how the system is functioning.[6]

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[5] Generators who produce and ship off-site less than 50 pounds of medical waste per calendar month are not required to initiate tracking forms, although they must keep a log that records waste shipments. Transporters who pick up waste from these generators are required to initiate manifests.

2. Proper Management of Medical Waste

EPA's regulations inaugurate a number of waste management requirements for generators, transporters, and TDD facilities. These requirements promote sound waste management throughout the regulated community. EPA has designed these standards as general performance standards.

Performance standards do not constrain the regulated community to a particular technology. They allow the regulated community the flexibility to develop a product or products that meets the prescribed requirements. For a demonstration program, during which the Agency is collecting information, studying the future of the program and learning about the regulated community, it is particularly important to foster development of technology that will aid proper waste management. Examples of these performance requirements are discussed in the following paragraphs.

- Generators must segregate regulated medical waste intended for off-site transport, to the extent practicable, into three categories – sharps, fluids and other medical waste. The segregation requirement raises institutional awareness of the types and quantities of medical waste generated and promotes development of appropriate management strategies for each medical waste category.

- Packaging must be rigid and leak resistant to ensure that waste handlers and the public will be protected from exposure to the waste. The packaging requirements can be met by a number of types of containers or container combinations.

- Storage requirements are designed to prevent unauthorized access to storage areas as well as to maintain proper sanitary conditions. The storage requirements preserve the integrity of the waste intended for shipment off-site, reducing potential occupational and accidental exposure.

- The labelling of medical waste simplifies waste identification without compromising its packaging, while marking requirements provide information about the waste and enable identification of generators, transporters and other handlers of medical waste.

- Transporter vehicle standards are designed to contain the waste and maintain packaging integrity during transport. The requirement that medical waste be protected from stress or compaction is particularly important for it lessens risks of exposure and leakage.

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[6] A detailed discussion of the data collected by EPA during the program's first reporting period is found in Section V.A. of this Report.

The medical waste program also includes performance standards designed to prevent incomplete treatment and destruction of waste. Unless the waste is incinerated or sent to a disposal facility, the program requires that waste must be both treated and destroyed before tracking ends. The terms "treat" and "destroy" are defined as performance standards that require the waste to be "treated to substantially reduce or eliminate disease causing potential" and "destroyed so that it is rendered unrecognizable." These general performance standards have had the effect of stimulating development of innovative treatment and destruction techniques.[7] The Agency has excluded compaction as a form of destruction. If a facility accomplishes only treatment or only destruction, but not both, it must continue to track the waste. Thus, waste remains within the tracking system [illegible] it poses any environmental or health threat.

3. Information Gathering, Research and Analysis

One of the primary reasons for developing a demonstration medical waste program was to facilitate the collection and analysis of information and data necessary for an informed discussion of the problems associated with medical waste. With this in mind, EPA is collecting information, and conducting data gathering, research and analysis in a number of areas. The focal points of the data gathering, research and analysis efforts are:

- The characteristics of the regulated community, including medical waste management practices;
- The physical, chemical, and pathological characteristics of medical waste;
- Treatment, destruction and disposal methods, including effectiveness and any associated health risks;
- Costs associated with the mismanagement of medical waste and with the requirements of the Act; and
- Enforcement and compliance with the MWTA requirements.

Each of these efforts is explained in greater detail below.

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[7] Additional information on treatment technology innovation is found on page 24 of this report.

a. Characteristics of the Regulated Community

Congress has recognized that the present program and future efforts will be far more effective if constructed with a thorough understanding of the practices of the community it seeks to regulate. It follows that a high priority of the medical waste program has been the development of sources of information regarding medical waste. The primary sources of information which the Agency has developed include:

- Transporter notification forms, which provide information about the universe of transporters;
- Transporter reports, which provide information about the entire medical waste management universe;
- On-site incinerator reports, which provide information about the medical waste that is incinerated on-site;
- Exception reports from generators and discrepancy reports from TDD facilities, which provide information about the efficacy of the tracking system; and
- Information collected by States, which will complement EPA's data gathering efforts (e.g., generator reports).

EPA has developed an automated information management system to manage data concerning generators, transporters and TDD facilities collected during the first six-month reporting period. The results of the data are summarized in Section V.A. of this Report.

b. Characteristics of Medical Waste Stream

At present, studies are underway to determine the chemical, physical and pathogenic characteristics of medical waste. EPA is conducting several studies using a variety of methodologies to develop such information both for medical waste in general and for medical waste which presents particular problems (e.g. waste from beach wash-ups).

A recently initiated Waste Characterization Study will analyze the generation of medical waste in order to determine the physical and chemical characteristics of the medical waste stream. Based upon a survey of existing data and the analysis of several representative facilities that generate medical waste, the major components of the medical waste stream, such as the plastic content of the waste stream, its moisture content, its heating value and other parameters, will be identified and analyzed. The study will also identify sources of radioactive and toxic constituents in the medical waste stream. The study is now underway, and its results will be presented in the Final Report to Congress.

The pathogenic characteristics of medical waste are currently being reviewed in EPA's Health Hazard Assessment.[8] This data will be used to assess the potential health hazards of exposure. By utilizing a "hazard assessment" methodology, this study will complement the epidemiological analysis conducted by the Agency for Toxic Substances and Disease Registry (ATSDR). The findings of the Health Hazard Assessment will be discussed in greater detail in the Final Report to Congress.

c. Information Concerning Sources of Medical Waste Contributing to Wash-Ups

Some information has already been collected regarding the composition of medical waste items found in beach wash-ups. As noted in the First Interim Report to Congress, information collected by six States for the 1988 beach season was analyzed and summarized in a Beach Wash-up Inventory Report.[9] According to the Report, over half the medical waste items collected were syringe-related. Such items are produced by a number of activities not regulated by the Act, i.e. home health care and illegal intravenous drug use.[10] Through its education and outreach efforts (discussed later in this Report) the Agency is involved in providing information to the home health care sector about proper medical waste disposal.

In order to identify the types, quantities, and sources of marine debris, and determine the extent to which such sources contribute to the problem of syringe-related medical waste wash-ups on beaches, EPA is conducting a number of studies. EPA's Office of Marine and Estuarine Protection has sponsored national beach clean-ups through an Inter-Agency Agreement with the National Oceanic and Atmospheric Administration (NOAA) and a grant to the Center for Marine Conservation (CMC). This activity involves the coordination of a volunteer effort (Citizen Pollution Patrols) to pick up trash from the nation's beaches during "Coastweeks." During the cleanup, volunteers characterize the trash by recording the types and quantities of debris on specially developed data cards. These data cards are returned to CMC and the information is entered into a national Marine Debris Data Base. The data from these cleanups is used to assess the types of debris present on beaches around the country, and will also be used in the future to monitor the effect of various control measures. The annual beach cleanups also serve to increase public awareness about the marine debris problem, and to clean temporarily our nation's coasts.

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[8] The Health Hazard Assessment is discussed in greater detail on pages 35-37 of this Report.

[9] U.S. EPA, Inventory of Medical Waste Beach Wash-Ups, June - October 1988. (Office of Policy Planning and Information, 1989). Information for this report was contributed by Connecticut, Maryland, Massachusetts, New Jersey, New York, and Rhode Island.

[10] A number of State reports concluded that these were the primary sources of the medical waste washing up on beaches in 1988. See Environmental Crimes Unit, Maryland Attorney General's Office, Medical Waste Investigation Report, (December 13, 1988).

EPA is also investigating floating debris in several harbors (Boston, New York, Philadelphia, Baltimore, Miami, Seattle, Tacoma, San Francisco, Oakland, and Galveston). The surveys often employ EPA's ocean survey vessel, the PETER W. ANDERSON. By towing surface nets through slicks of floating debris, collecting the debris and sorting, identifying, and counting the resulting materials, EPA has gathered information regarding the nature of floating debris in these areas. This information is invaluable in the assessment of harbors as potential sources of debris to other coastal areas. Interestingly, of the syringes found during the Harbor Studies Program, all were the small insulin-type, not hospital-type hypodermic needles. More detailed information about the syringes found during the study is set forth in Appendix 1 of this Report. EPA is expanding these surveys offshore to determine the extent to which materials in the harbors are being transported into the open ocean.

Syringes collected during the EPA Harbor Studies Program also were preserved and the contents analyzed to help determine potential sources of the syringes. Chemical analyses of a few of these syringes have identified insulin and cocaine. Additionally, the types of syringes found suggests that the source of much of the medical waste found on beaches may be household users which are excluded from regulation by the MWTA (See Appendix 1). Further analysis of these samples will be included in the Final Report to Congress. More recent information which States have collected regarding the composition of beach wash-up waste also will be compiled and, if appropriate, included in the Final Report. EPA also is preparing a separate report on results of the Harbor Studies Program.

EPA's Office of Marine and Estuarine Protection also is proceeding with studies to determine the types and amounts of materials entering the marine environment from publicly owned treatment works (POTWs), combined sewer overflows (CSOs), and storm sewers. EPA's studies involve collecting samples using nets placed on CSO and storm sewer outfalls, and by collecting floatables directly from POTW settling tanks.[11] The New York City Department of Environmental Protection also conducted two surveys in 1988 to determine if medical waste enters the water pollution control plants.[12] The studies involved examining screenings and skimmings at 14 treatment plants for the presence of medical wastes. The data from one survey (July of 1988) indicated that 119 syringes are collected by all 14 treatment plants daily, while data from the other survey (August of 1989), which was collected after a significant rainfall, indicated that only 12 syringes are captured daily by all 14 treatment plants.

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[11] U.S. EPA. 1990. Methods to Manage and Control Plastic Wastes, Report to Congress. Prepared by the Office of Solid Waste and Emergency Response and the Office of Water. EPA/530-SW-89-051. p. 3-14.

[12] New York City Department of Environmental Protection, Medical Waste Study 41-46 (1989).

Although POTWs are potential sources of floatables in the marine environment, EPA emphasizes that if POTWs are properly operated, they should not discharge floatable debris into the marine environment. However, under some circumstances, plastics materials disposed into sanitary sewers can be discharged to marine waters. These circumstances, which are not common, include:

- Malfunctions or breakdowns. During periods of "down-time," when a POTW is not operating because of malfunctions or breakdowns, influent may circumvent the treatment system and be released into receiving waters; and

- Bypasses. At POTWs that cannot treat the capacity of "normal dry-weather flow," untreated sewage may bypass treatment and be released directly into the receiving waters; and

- CSOs. In a community where both sewage and stormwater runoff are combined into one system and the volume of stormwater exceeds a treatment plant's capacity (e.g., during heavy rain), both untreated sewage and stormwater are discharged directly into receiving waters.

A study prepared by the New York Department of Environmental Conservation (NY DEC)[13] also cited CSOs, raw sewage discharges caused by breakdowns at waste water treatment plants, and stormwater outlets as likely sources of floatable debris.

According to the NY DEC report, and reports prepared EPA Region II,[14] data suggests that a major source of the debris that washed up on New York and New Jersey beaches in 1988 and earlier was solid waste containing syringes that was improperly managed at marine transfer stations, at Fresh Kills landfill, and on barges enroute to Fresh Kills landfill. Local municipalities have initiated steps to correct this problem. The City of New York and the State of New Jersey have entered into a judicial consent decree which directs waste handling activities. The consent decree, aimed at reducing the amount of debris entering the marine environment, includes strict waste handling protocols, use of containment booms around loading and unloading facilities, use of barge covers, and frequent removal of floating debris within the containment booms.

A general conclusion can be drawn from these studies -- syringes can be found throughout the near-shore marine environment in very low numbers, and medical waste is a very minor component (<0.1%) of all floating debris. Furthermore, the data suggests that the debris is entering the marine environment in several ways including storm sewer outfalls, CSOs, general litter, and improper management of municipal waste containing insulin syringes.

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[13] NYDEC. Investigation: Sources of the Beach Washups of 1988, (November 1988).

[14] U.S. EPA. Floatables Investigation. Report, (prepared by the EPA Region II) (1988). U.S. EPA. Methods to Manage and Control Plastic Wastes, Report to Congress EPA/530-SW-89-051, 3-10. (Prepared by the Office of Solid Waste and Emergency Response and the Office of Water) (1990).

d. Information Concerning Treatment, Destruction and Disposal Methods

Initially, research concerning treatment, destruction and disposal methods consisted of an assessment of the advantages and disadvantages of the existing principal technologies and of the factors affecting their effectiveness. The results of this research were presented in the First Interim Report to Congress.[15] Research in this area continues; in particular, criteria are being developed to evaluate emerging new treatment technologies.

The physical and chemical composition of the medical waste stream will have significant implications for the effectiveness of any treatment technology. The Waste Characterization Study will collect empirical data regarding the composition of medical waste. These waste composition characteristics are variables that will be considered in the assessment of treatment technologies, which will be included in the Final Report to Congress.

Current research has focused on the most commonly used treatment technologies and their potential health effects. These technologies will be tested using particularly resistant indicator microorganisms to evaluate their effectiveness in destroying pathogens. This analysis will also help to identify possible routes of transmission for microorganisms both during the primary treatment process and any subsequent treatment and disposal activities (e.g., off-site transport). This information will be considered by the Agency's Office of Air and Radiation in its deliberations on whether there is a need for regulation of medical waste incinerator emissions.

Additionally, EPA's Office of Solid Waste and Office of Air Quality Planning and Standards are undertaking a joint testing program to evaluate emissions from typical existing incinerator units and to determine the effects of variations in operating conditions. Other studies, conducted jointly by the State of California Air Resources Board and EPA's Office of Research and Development, led to the publication of a report entitled State-of-the-Art Assessment of Thermal Treatment of Medical Waste. The report addresses the problems of on-site hospital incinerator operation and presents options available to incinerator operators. The State of California set its operation and emission standards based on the data and information presented in the report.

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[15] See also U.S. Environmental Protection Agency, Office of Air and Radiation. Hospital Waste Combustion Study: Data Gathering Phase. EPA-450/3-88-017, (December 1988).

The disposal of untreated medical waste in landfills is an increasingly uncommon practice, as the First Interim Report to Congress observed. The most significant health risks associated with such disposal may be occupational risk to waste handlers and risks faced by children playing at landfills and disposal sites. Furthermore, the information currently available concerning pathogen survivability and behavior in landfills may not be applicable to the pathogens found in medical waste. Information from the Health Hazard Assessment may provide further insights into this area.

The disposal of certain types of medical waste into wastewater treatment systems (most notably blood and blood products) is under Agency review. At least one State (New Jersey) and several local jurisdictions are concerned about introduction of medical waste, especially syringes, into the wastewater treatment system. With this in mind, EPA's Office of Water will evaluate discharges of medical waste to sewers, and examine the efficacy of existing Federal, State and local requirements and controls.

Recognizing that waste disposal problems can be minimized by encouraging source reduction and reduction in the toxicity of wastes, EPA has been investigating the applicability of such measures to medical wastes. The Waste Characterization Study will analyze options for reducing the amount of waste generated and will identify opportunities for reducing the toxic constituents of waste items (e.g., product reformulation to minimize toxic components).

e. Cost Analysis

The First Interim Report contains EPA's preliminary analysis of the costs of the medical waste program to the regulated community and improper management of medical waste. Costs were not estimated for administration of the program by EPA and the covered States. Since the submission of the First Interim Report, data collection efforts have continued, but no new analyses are discussed in this Report.[16] The Final Report to Congress will incorporate analysis of the recently collected data on generators, waste quantities, and transportation practices in its discussion of the costs of the medical waste program to the regulated community.

The final analysis of the cost to the regulated community of the tracking rule will be influenced by the additional data collected about the characteristics of the regulated community. Changes in the cost of medical waste transportation and disposal as a result of the medical waste program will also be taken into consideration; this information may be primarily anecdotal.

With regard to the costs to human health, local economies and the environment from medical waste mismanagement, in the Final Report EPA will examine state and local efforts to assess the impacts of beach wash-ups on local economies. An attempt will be made to include economic evaluations of the human health and environmental impacts of improperly managed medical waste as well, although this information will necessarily tend to be less quantifiable.

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[16] Please refer to page 37 of this Report for additional information about EPA's cost analysis studies.

f. Enforcement and Compliance

Information concerning the enforcement of the MWTA and the degree of compliance with its requirements in covered States is being collected to support the program's evaluation of its enforcement strategy. Furthermore, information concerning enforcement and compliance monitoring of medical waste programs in noncovered States is being collected to provide insights about other medical waste management strategies.

The covered States and EPA Regions are compiling quantitative data concerning the number of inspections conducted, the number of violations found, the enforcement actions undertaken, and other enforcement-related information. Appendix 2 sets forth data about the program's enforcement efforts.[17] This data is being compiled on a computerized information management system, which will be discussed in greater detail later in this Report and in the Final Report to Congress.

Furthermore, EPA has established a Compliance Monitoring and Enforcement Information Clearinghouse to promote the collection and exchange of enforcement-related information. The Clearinghouse collects and catalogues complaints, inspection reports, press releases, notices of violations and other relevant material from a number of covered and noncovered States, and distributes a bibliography of materials.

State and EPA Regional officials may request copies of any Clearinghouse materials. The Agency anticipates that States will be able to carry out more effective, aggressive enforcement than they otherwise would, because they will have enforcement materials from the Clearinghouse available to help them develop an enforcement strategy and prepare enforcement cases. Additionally, these materials have been used to prepare this Report and will be utilized in preparing the Final Report to Congress.

4. Outreach, Education and Training

An effective medical waste program must be well-understood by the regulated community (e.g., physicians, dentists, medical clinics, hospitals, nursing homes); it also must have well-established communications links with other regulatory agencies performing similar or complementary functions. With this in mind, program outreach, education, and training has been focused in five primary areas:

- Outreach and education for the regulated community;

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[17] These charts and other enforcement data are discussed on pages 20-22 of this Report.

- Outreach and education for the unregulated universe, including individuals who use items such as syringes, lancets or other medical implements, but are not subject to the Act (e.g., home health care), and the general public;
- Integration and coordination with other Federal and State agencies;
- Within the program, outreach and coordination between EPA Headquarters, EPA Regions, and States; and
- Education and training for Federal and State program personnel who administer and implement the program.

These five primary areas are discussed in greater detail below.

a. Outreach and Education for the Regulated Community

Since the commencement of the medical waste program, EPA has emphasized outreach to and education of the regulated community. Intensive and ongoing outreach to the regulated community has been designed to encourage dialogue, promote understanding of program requirements, and cultivate a high level of voluntary compliance. An initial program priority was the production of high-quality written materials outlining the specific requirements and responsibilities of generators, transporters, and TDD facilities. These instructional materials have been distributed widely. Appendix 3 contains examples of instructional materials prepared by EPA.

The distribution of these booklets has been facilitated by a large-scale program of presentations to the regulated community. EPA Region I and Region II have co-sponsored programs with the covered States. Personnel from EPA Headquarters and Regions frequently give presentations at trade association meetings. New York, New Jersey, Puerto Rico, Rhode Island and Connecticut have each undertaken presentation programs; EPA personnel have participated in many of these presentations, outlining the Federal program and responding to the questions and concerns of the regulated community. At the time of submission of this Report, at least 45 presentations had been held. EPA is also continuing outreach to segments of the regulated community that are highly regulated, and therefore known to EPA, such as medical waste transporters and hospitals that operate on-site incinerators by sending booklets and letters reminding them of the periodic reporting requirements.

Several outreach efforts are now planned for additional segments of the regulated community. States have indicated that outreach to various professional organizations (e.g. American Medical Association) can enhance compliance; EPA personnel currently are considering the initiation of such efforts. As the volume of interstate shipments of medical waste increases, outreach to TDD facilities will receive more attention. Finally, various informational materials are being translated into Spanish to facilitate outreach efforts in Puerto Rico.[18]

b. Outreach and Education for the Unregulated Universe

In order to address an important Congressional concern regarding waste generated outside the scope of the Act, EPA has conducted outreach to explain proper disposal techniques to individuals who use medical implements such as syringes in the home. The home health care community is the most significant unregulated community that EPA has attempted to reach because some of the medical debris discovered on beaches has been linked to disposal of insulin syringes. The means by which insulin syringes could end up on a beach are discussed in section III.B.3.c.

Substantive guidelines have been developed for the disposal of home health care medical wastes; these were presented in the First Interim Report to Congress. Since the submission of the First Report, the guidelines have been written in brochure form and distributed to EPA Regional personnel, States, professional organizations and health care professionals.[19] Appendix 4 contains EPA's pamphlet entitled "Disposal Tips for Home Health Care." The guidelines are expected to advance proper waste management in the home and encourage health care professionals to educate their patients regarding proper medical waste management practices.

Outreach also has included providing medical waste-related information to the general public and the media to clarify the actual and potential hazards present. Agency personnel have conducted lectures at medical schools to instruct medical students concerning proper medical waste management practices.

In order to reach children and individuals with low literacy skills, the Agency is currently developing an instructional pamphlet to teach juveniles (such as diabetics) about proper disposal of sharps, such as syringes and lancets. The Agency expects this pamphlet to be distributed in Fall, 1990.

Incinerator operator training is a crucial variable influencing the effectiveness of medical waste incineration. Therefore, the Agency has developed a Medical Waste Incinerator Operator Training Course. The course materials have been distributed to all the States, and they were encouraged to conduct or require operator training as part of their regulatory or permitting programs.[20] Additionally, EPA presented a workshop on medical and institutional waste incineration six times in the past year at various locations across the United States.[21]

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[18] The materials that will be available in Spanish include the informational booklets for generators, transporters, and TDD facilities; the MWTA interim final rules; and the interpretive question and answer memoranda produced by the Agency and discussed in d. below.

[19] 25,000 copies of the brochure (EPA/530-SW-90-014A) and 160,000 copies of the flier (EPA/530-SW-90-014B) have been produced.

c. Integration and Coordination with Other Federal and State Agencies

From the early stages of its development, EPA has recognized that interagency coordination is a cost-effective method of increasing program implementation. EPA sought and received input from several States and Federal agencies which has been crucial to the initial development of the program.

As the program has matured, the Agency has been particularly attentive to the relationship of its regulations, standards, and activities with those of other Federal agencies such as the Centers for Disease Control (CDC), the Agency for Toxic Substances and Disease Registry (ATSDR), and the Occupational Safety and Health Administration (OSHA). In particular, pursuant to its blood-borne pathogen standard, OSHA has begun to regulate many of the same facilities that fall under the MWTA rules. The Agency recognizes the importance of the relationship between the MWTA regulations and OSHA's regulations.[22]

EPA has also attempted to work with appropriate agencies in noncovered States to aid program implementation. This is particularly important for several reasons. First, EPA's enforcement strategy encourages the States to initiate enforcement actions; EPA Regions will provide assistance or, in certain cases outlined below, may take direct action. Second, transporters cross State boundaries and TDD facilities are found in both covered and noncovered States. Thus, in order to implement the program consistently, an active State/Federal partnership is essential.

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[20] U.S. EPA, Control Technology Center: Operation and Maintenance of Hospital Medical Waste Incinerators, March 1989, EPA-450/3-89-002; Hospital Incinerator Operator Training Course: Volume I (Student Handbook), March 1989, EPA-450/3-89-003; Hospital Incinerator Operator Training Course: Volume II (Presentation Slides), March 1989, EPA-450/3-89-004; Hospital Incinerator Operator Training Course: Volume III (Instructor Handbook), March 1989, EPA-450/3-89-010. Volumes I and II are available through the National Technical Information Service. For those interested in conducting the course, Volume III and the course projection slides are available through the EPA Air Pollution Training Institute.

[21] U.S. EPA, Center for Environmental Research Information, Seminar - Medical and Institutional Waste Incineration, CERI 89-247, (November 1989).

[22] OSHA's Bloodborne Pathogen Standard (54 Fed. Reg. 23042-139 (May 30, 1989)) was published as a proposed rule and is expected to be finalized by January, 1991. It applies to health care workers who come in contact with infectious or potentially infectious body fluids.

Representatives of interested States and EPA Regions have been invited to participate in program training activities (see below).

d. Internal Program Coordination

The medical waste program has led to the development of a number of innovative structures to ensure rapid and effective communication between EPA Headquarters, EPA Regions and States.

Periodic Federal/State roundtable meetings have provided invaluable opportunities for information exchange, feedback, and program development. The first such roundtable was held in Washington, D.C. shortly before program implementation; the second took place in New York City in November, 1989; the third was held in Washington, D.C. in June, 1990; and the fourth was held in Boston, Massachusetts in August, 1990.

As a result of a suggestion made at the first roundtable, EPA Headquarters developed an ongoing series of interpretive Question and Answer Memoranda. These Memoranda have provided the States and EPA Regions with interpretations of difficult questions about the MWTA rule and have also been made available to the regulated community.

States often have similar concerns about medical waste; they also may have unique interests and resources. EPA encourages innovative projects and initiatives, which can provide useful information, complement other program activities, and serve as "experiments" with potentially significant implications for future national action. The Agency set aside nearly $800,000 for project-specific grants available to all States, both covered and noncovered. A total of 16 proposals were submitted by 10 States. These proposals were reviewed by a committee of representatives from EPA's Office of Waste Programs Enforcement, Office of Solid Waste, Region IV and the State of Utah. Nine proposals were selected based on their ability to complement and extend other program activities and the lack of alternative funding sources. States will provide 5% of the funding for each project. These selected proposals are listed and described in Appendix 5.

e. Education and Training for Federal and State Program Personnel

The thorough education of Federal and State personnel implementing the medical waste requirements has been an important element of the program. This training has been directed at inspectors and their supervisors as well as program managers. There are four primary objectives of the training provided to these personnel:

- learning health and safety techniques to assure personnel health and safety;

- understanding the unique characteristics of medical waste and the regulated community;
- increasing the effectiveness of enforcement activities; and
- certifying field inspectors to conduct inspections in accordance with applicable OSHA and State occupational health directives.

These objectives are clearly interconnected. For example, inspectors who are aware of the unique characteristics of medical waste will be prepared to protect themselves against exposure to the waste, and also to conduct more effective inspections.

Several training initiatives have been undertaken since the initial development of the medical waste program. In May and June, 1989 a one-day health and safety course was offered twice to EPA, State and contractor personnel. In the Fall of 1989, a one-day course was developed and presented which specifically addressed enforcement issues related to the MWTA regulations as well as presenting health and safety training specifically targeted to medical waste inspectors. Encouraged by the positive reactions to this course, an expanded two-day Medical Waste Enforcement Workshop has been developed and is being presented to State and Federal personnel in four locations. The course teaches inspection and investigation techniques, reviews the Federal medical waste program, presents health and safety training, and acts as a forum for idea exchange between EPA and State personnel.

5. Enforcement Strategy

The MWTA contains strong enforcement authorities. It empowers EPA, or its duly designated representative, to conduct facility inspections and request information about the generation, storage, treatment, disposal or handling of medical waste for purposes of developing, or assisting in development of, any regulation or report, or for enforcing the provisions of the Act. The Agency or its representative also can conduct monitoring or testing, take samples, and have access to all facility medical waste records.

Compliance orders can be issued to any violator of the Act assessing a civil penalty and requiring compliance with the law and regulations. The Act allows the Agency to assess and seek civil penalties of up to $25,000 per day for each violation. In the event that records, reports, documents or material information is knowingly falsified, or the provisions of the Act or rule are knowingly violated, the MWTA incorporates criminal sanctions subjecting the convicted violator to a fine of not more than $50,000 per day of violation or imprisonment of up to 5 years. If any person knowingly creates a situation that places another person in imminent danger of death or serious bodily injury, a criminal fine of up to $250,000 or imprisonment of up to 15 years may be imposed. Under this provision, a defendant organization may receive a criminal penalty assessment of up to $1,000,000.

Based on these strong enforcement authorities and the goals of the MWTA, EPA has developed an enforcement strategy designed to promote rapid and widespread compliance with the medical waste program. The strategy encourages States to lead enforcement efforts with EPA support. According to the strategy, the Agency's enforcement role includes:

- developing enforcement guidance so that the objectives of the Act are carried out;
- developing handbooks, brochures, and other informational materials to encourage widespread voluntary compliance;
- maintaining databases, including transporter notifications and reports and incinerator reports; and
- handling specific cases involving potential violations.

In the long term, States will take the lead in conducting inspections and bringing enforcement actions. Initially however, EPA is taking a major role in enforcement, especially in Region II, until States can obtain necessary enforcement personnel. To strengthen enforcement of the Act, the interim final rule establishes the presumption that any regulated medical waste found at a facility in a covered State is presumed to have been generated in that State. Furthermore, the MWTA provides that States may use applicable State authority or Federal authority to pursue enforcement.

During the first year of the program, EPA has actively enforced the Act and regulations. The Agency has conducted inspections and taken enforcement actions in both covered and noncovered States, and coordinated its enforcement activities with State personnel. Thus, EPA has played a large role in enforcement during the program's start-up phase. In the second year, EPA enforcement initiatives will be targeted to support state enforcement actions in situations in which States solicit EPA intervention. Although the Agency anticipates relatively little Federal enforcement action in States that are implementing an effective program, EPA involvement may be appropriate in the following circumstances:

- during the start-up phase of the program;
- at Federal facilities, if the State requests EPA assistance; and
- in following up on regulated medical wastes transported to noncovered States and to Indian tribal lands where there is no comparable state or tribal statute.

Enforcement efforts during the first twelve months of the medical waste program are summarized in Appendix 2. The Agency has aggressively pursued serious violators (11 administrative actions have been undertaken) and has issued 257 warning letters or notices of violation for less serious infractions. As of June 1, 1990, approximately 510 inspections had been conducted and approximately $690,000 in penalties have been assessed.

IV: RESULTS OF THE PROGRAM AND ISSUES FOR FUTURE CONSIDERATION

The medical waste program was established approximately one year ago. At this point, it is premature to examine the program's success, although the available evidence indicates that the program has already had a number of direct and indirect effects on the management, handling and disposal practices of medical waste. These results are discussed in this Section. The Final Report to Congress will contain a detailed examination of the program's success and a more thorough review of its effects.

The regulation of medical waste also has raised a number of issues that will need to be addressed as part of any review of the future of medical waste regulation. Some of those issues are discussed in this Section. Other issues will be set forth in the Final Report to Congress.

A. Direct Program Effects

Several results of the medical waste program are direct and relatively clear. The most significant include the implementation of a functioning demonstration tracking program and the collection of essential information.

1. Demonstration Tracking Program

A coordinated, functioning Federal demonstration tracking and management program has been established and seems to be successfully tracking the management and disposal of medical waste in the States it covers. The management performance standards which this program contains are leading to the development of model practices within the regulated community to ensure the proper handling and management of medical waste. The demonstration program also has raised awareness about existing and potential treatment technologies and has led to studies about their benefits and drawbacks.

2. Information Collection

Information collected pursuant to the program is expanding the Agency's knowledge concerning the nature of medical waste and the universe of medical waste generators, transporters, and TDD facilities. Although some of this information has been included and analyzed in this Report (see Appendix 6 and Section V.A.), the Final Report will contain a comprehensive review and analysis of much additional information. Data collection and analysis will facilitate more informed discussion of Federal medical waste regulation.

B. Indirect Program Effects

In addition to its direct effects, the medical waste program seems to be having several indirect effects, which include the encouragement of innovation in treatment technologies, the reevaluation of home health care waste management, some reduction in the severity of beach wash-ups, and the contribution to program development in noncovered States and foreign countries. The program will provide, to the extent possible, further analysis of these indirect effects in the Final Report to Congress.

1. Treatment Technology Innovation

The medical waste program provides an exclusion from the tracking requirements for medical waste that has been both treated and destroyed. This exclusion has encouraged the development of innovative treatment and destruction technologies.

New treatment technologies for medical waste are often adapted from other uses. For example, gamma irradiation, which has been used to sterilize reusable medical instruments, is now being developed for medical waste treatment. Microwaving techniques are also being adapted for treating medical waste.

Most of the innovative treatment methods are for the treatment and/or disposal of sharps and are being developed for the small quantity generator (i.e., physicians', dentists', or veterinarian's offices). The Agency is in the process of developing a program to evaluate these systems to ensure that they meet the definitions of treatment and/or destruction found in the interim final rule. The Agency does not have the explicit authority under the MWTA, however, to "approve" or "certify" these technologies.

2. Home Health Care

The program has encouraged a reevaluation of home health care waste management. Although the Agency has not documented changes in waste disposal practices, it believes that its education and outreach efforts targeted at persons generating home health care waste, along with publicity about the sources of waste contributing to the problem, are likely to have a positive impact in the way home health care wastes are disposed of.

3. Beach Wash-ups

It is not possible to correlate directly the effects of the program with the number of beach wash-ups or the amount of medical waste on beaches. The frequency and severity of beach wash-ups are influenced by many factors, many of which whose study are beyond the scope of the Act, including weather patterns, management practices for municipal solid waste, and the amount of medical waste (or "look-alike" waste) disposed of in sewers and on the streets. Nevertheless, it is likely that the program may be responsible for reducing the severity of beach wash-ups by increasing awareness of the problem and its sources among health care providers, the public and local government.

By encouraging good waste management practices among the regulated and unregulated (e.g., home users) communities and by publicizing the problems associated with improper management, the Agency believes that the program decreases the amount of medical waste that is disposed of improperly. Furthermore, EPA is conducting or sponsoring a number of projects that address the problem of floating debris in general, of which medical waste is one component. These include National Beach Cleanups, the National Harbor Surveys, and the "Floatables Action Plan" in New York and New Jersey. Additionally, the publicity generated by these programs may indirectly influence more responsible behavior.

4. Contribution to Medical Waste Program Development

Concern over medical waste management and Federal action, including the implementation of the medical waste program, has spurred a flurry of activity both in other States and other nations. Additionally, the Federal program has influenced medical waste programs in the covered States. The number of States regulating medical waste and the comprehensiveness of such programs are growing rapidly.

According to the National Solid Waste Management Association, medical waste regulation has greatly expanded since July, 1988[23]. Since that time:

- 8 states have passed medical waste legislation;
- 10 states have promulgated new or revised regulations;
- 4 states have passed new laws and promulgated regulations.

Significantly, at least twelve states recently have begun to track medical waste via a manifest system.

The covered States have amended their regulatory programs in light of the Federal program. Additionally, some of the covered States have moved to regulate areas that are not controlled by the Federal program. The Final Report to Congress will discuss in detail the changes in the covered States' programs.

The program has also attracted interest from several other countries. Australia has recently implemented a medical waste tracking and management program quite similar to the EPA's program; Canada and Japan have expressed interest in the program as well.

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[23] National Solid Waste Management Association, Special Report: Medical Waste Management (1989).

C. Issues For Future Consideration

1. Introduction

Since the commencement of the medical waste program approximately one year ago, a number of issues have emerged that relate to the future of the program. These issues are discussed below and will be elaborated further in the Final Report. The Final Report will also address other issues that may arise in the second year of the demonstration program.

In the Final Report, the Agency will evaluate more fully the success of the program in controlling mismanagement of medical waste and make recommendations on the need for, and content of, future Federal regulations regarding medical waste.

2. List of Issues

a. Developing a Uniform Definition of Medical Waste

Developing a uniform definition of medical waste that is easy for the regulated community to understand and implement and for EPA to enforce has been problematic. Since promulgation of the rule, the regulated community has often requested interpretations of the definition of medical waste. In particular, the Agency has noted confusion among generators regarding certain waste items, including:

- the scope of the blood products category (which lists "... items that are saturated and/or dripping with blood..."); and
- the status of personal care items generated by a patient that are unrelated to the condition being treated (such as a disposable razor).

Generators are uneasy because they are required to use their best judgement in some cases to determine whether a specific item is regulated, and they fear that an incorrect decision will lead to possible enforcement action.

b. Use of Aesthetics as a Criterion to Regulate Medical Waste

The MWTA gives EPA broad authority to regulate medical waste. In its interim final rule, EPA has used aesthetic concerns as one criterion for determining what to list as a regulated medical waste in addition to health criteria. Some of these determinations have been controversial. For example, discarded intravenous bags are considered medical waste, even if they contained sterile solutions and pose little or no risk to human health.

c. Other Sources of Medical Waste

Congress enacted the MWTA because of widespread concern about beaches polluted with medical debris such as syringes. At present, the extent to which sources that are excluded by the MWTA (and are therefore not regulated under this program) contribute to the problem of beach wash-ups and other mismanagement incidents is unclear. Examples of unregulated sources include wastes such as syringes that are generated in the home or on city streets by drug users and are improperly disposed of (e.g., onto the ground or into storm water systems), or properly disposed of and subsequently mismanaged (e.g., into household trash) and medical items that are discharged to sanitary sewers and may be released through CSOs or other means.[24] EPA has attempted to address home health care waste sources through its outreach efforts (see pages 17-18). Its home health care booklet was written to provide guidance for appropriate waste disposal.

In 1988, the Clean Water Act was amended to prohibit the discharge of medical waste to navigable waters.[25] EPA's Office of Water is currently evaluating alternatives to implement these amendments.

d. Refining and Improving the Tracking System

The current paper-based tracking system, which revolves around the manifest, has been subject to a large number of "paper discrepancies." These are discrepancy reports that are caused by mere human error and not illegal activity. They occur for several reasons, including miscounting the number of boxes in a waste shipment or improper affixing of labels to boxed waste.

These types of discrepancies are not surprising. A single truck may contain several hundred boxes of medical waste, and the waste may originate from many generators and therefore be accompanied by several manifests. The result is increased unloading time and paperwork burden on waste handlers, and a strain on Federal and State enforcement personnel who must track down and resolve these discrepancies, taking away valuable time from situations in which investigation and enforcement are clearly warranted. EPA is investigating other options for tracking waste, and will recount its results in the Final Report.

e. Inadequacy of the Data to Address Certain Issues Listed by Congress in the MWTA

Despite the broad information gathering power in the MWTA, because of inadequacy of data EPA has not been able to address adequately some of the questions on which it is required to report to Congress. For example, EPA has not been able to quantify risks to human health and the environment posed by mismanagement of medical waste because information necessary for a quantitative health assessment, such as the types and quantities of pathogens found in waste, survivability of pathogens in the environment, infective dose of specific pathogens, and general information on exposure to medical waste, is lacking or is not in a usable format. This lack of information led the Agency to conduct a qualitative health assessment rather than a quantitative one. In section V.B. of this Report, EPA provides an update on its plan to conduct a qualitative health assessment. The Agency's qualitative assessment will attempt to address some of the concerns raised by Congress. This lack of data also affected ATSDR's study of the health effects of medical waste on waste handlers. In that study, the epidemiological data used to develop rates of disease and injury pertained mostly to HIV (Human Immunodeficiency Virus or the AIDS virus) and HBV (Hepatitis B virus), and was not related specifically to medical waste.

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[24] A more detailed discussion of the sources of wastes that contribute to beach wash-ups is found on pp. 10-13.

[25] The discharge prohibition is contained in Section 3202 of Title III of the Ocean Dumping Ban Act of 1988, Pub. Law 100-688, which amended the Clean Water Act.

Collecting pre-MWTA baseline information on topics such as waste generation, waste management practices, and waste management/disposal costs has been problematic. This information is necessary to assess changes attributable to the demonstration program. This is because most facilities (especially small quantity generators) generally did not maintain records of their waste disposal practices prior to implementation of the demonstration program, and because waste management practices vary widely between facilities and are driven by factors other than Federal regulations such as availability and cost of disposal options, and State and local regulations. The information that the Agency has collected has been largely anecdotal.

This lack of data further explains, in part, the broad spectrum of opinion that exists on whether medical waste poses a potential health problem, and the extent to which medical waste should be regulated, if at all.

f. Standards for Waste Treatment, Destruction, and Disposal Facilities

There are no provisions in the MWTA that explicitly empower the Agency to promulgate treatment and disposal standards or TDD facility standards; EPA has not included such standards in the current federal regulations. Rather, EPA has defined the terms "treatment" and "destruction" in general terms, and has not established objective (i.e., measurable) standards for determining when a waste has been both treated and destroyed (and therefore excluded from further regulation). In fact, EPA has not concluded that treatment and/or destruction standards are needed considering the fact that the risks posed by mismanagement of medical waste are not well understood (but appear likely to be minimal). Furthermore, EPA has not concluded that the presence of physical hazards alone (e.g., exposure to syringes or glassware) warrant regulation up to the point where the waste is destroyed. The Agency is assessing whether there is a need to regulate the discharge of medical waste to sanitary sewers. The data gathered during this first year of the program suggests that liquid medical wastes (e.g. blood, blood products, and other fluids) are commonly disposed of into waste water treatment systems in some areas.

g. Nationwide Consistency in Medical Waste Management

In the absence of a federal program, States and municipalities will continue to pass laws and promulgate regulations regarding medical waste. A waste transporter or TDD facility that conducts its business across state boundaries thus will be faced with complying with numerous (potentially conflicting) medical waste programs. Congressional testimony has revealed that substantial costs could be imposed upon the regulated community if it were forced to comply with a patchwork of medical waste programs[26]. Also, it has become clear from the reports submitted by transporters that much medical waste is shipped across State boundaries. Because State authority generally ends at its boundaries, it may be difficult for a State to conduct compliance monitoring and enforce its program if medical waste is shipped out-of-state.

EPA has not determined whether a federal program is desirable to impose regulatory uniformity and consistency. Such a program could contain provisions such as uniform tracking, management standards and other requirements, and enforcement authorities that reach beyond state boundaries.

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[26] See Infectious Waste - 1-Year Update on Practices, Policy, and Public Protection: Hearing Before the Subcommittee on Regulation and Business Opportunities of the House Committee on Small Business, 101st Cong., 1st Sess. 40, 45 (1989).

V. RESEARCH UPDATE AND FORECAST

The Act requires EPA to report on 12 specific areas regarding medical waste. Much of this information is presented in the Sections I through IV of this Report; for ease of reference, however, this Section presents this information according to the 12 Chapters of the First Interim Report and provides details about the Agency's future activities.

A. Update of Chapter 1, Characterization of Medical Waste

1. Overview of Characterization Efforts

In the First Interim Report to Congress, EPA presented preliminary estimates of the numbers of generators potentially affected by the rule and the quantities of regulated medical waste generated in the covered states and nationwide. EPA also provided preliminary figures on the number of transporters handling and transporting regulated medical waste.

In the First Interim Report, the Agency also explained its long-term strategy for collecting data to characterize more fully and accurately the generation and management of medical waste through reporting requirements included in the interim final rule.

Specifically, the rule requires transporters who carry medical waste generated in a covered State and medical waste generators with on-site incinerators which are located in a covered State to submit periodic reports to the Agency. The rule includes three reporting requirements:

- the Medical Waste Transporter Notification;
- the Semi-Annual Medical Waste Transporter Report; and
- the On-Site Medical Waste Incinerator Report.

These reports, collectively referred to as the Medical Waste Reports, were designed to address several basic questions regarding the generation and management of medical waste, including:

- What are the types and numbers of facilities that generate medical waste?
- What types of generators produce medical waste and how much regulated medical waste is generated by each of the generator types? What would be the effect of excluding small quantity generators (e.g., less than 50 pounds per month) from regulation?
- What treatment and disposal practices are currently in use?

- What quantity of waste is transported off-site for treatment or disposal?
- What quantity of waste is treated or incinerated on-site?
- To what extent is medical waste shipped out-of-state for disposal?

The first reporting period began in June, 1989[27] and ended in December, 1989. Reporting data was due to the Agency in February, 1990. This update presents the results from the first reporting period, and describes the activities that EPA will be undertaking in the future to characterize generation, management, transportation and disposal practices.[28]

2. Utility and Limitations of the Data Collected from the Medical Waste Reports

To facilitate data processing, EPA developed an automated information management system that supports data entry, tracking the status of forms, issuance of identification numbers and reporting of summary data. To date, EPA has received and processed 215 transporter reports (or letters) and 252 on-site incinerator reports. EPA believes that this represents a response rate of approximately 90% for transporters for the first reporting period. The response rates for on-site incinerators have not been estimated because the Agency has not determined the size of the regulated universe. We do believe, however, that the response rate for large facilities (e.g., hospitals) is high because the number of hospitals is known, and most (>85%) were either listed on transporter reports, or submitted an on-site incinerator report.

EPA believes that the results presented in Section 3 (below) provide a relatively accurate picture of the numbers and types of medical waste generators who either ship waste off-site or incinerate waste on-site; the number and types of treatment and disposal facilities; and the number of transporters who haul medical waste off-site. The Agency also believes that general conclusions about the covered States can be drawn from the quantity information, such as the percentage of regulated medical waste that is incinerated on-site, the percentage of all regulated medical waste that is generated by each generator type, and the percentage of regulated medical waste that is generated by small quantity generators.

There are, however, limitations on specific conclusions that can be drawn from the data. For instance, the total quantity of medical waste generated (and therefore waste generation rates) is likely underreported for the first reporting period because, early in the effective period of the regulation, many generators may not have properly segregated medical waste, or properly maintained records, or initially used a transporter who had notified EPA.[29]

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[27] The first reporting period began in July 1989 for Puerto Rico and Rhode Island because they entered the program one month later than Connecticut, New York and New Jersey.

[28] Exhibits that compile the data collected during the first reporting period are presented in Appendix 6.

Additionally, there are some generators and some waste quantities that are not captured by the Medical Waste Reports because of statutory exclusions or exemptions included in the rule. For example, quantities of medical waste disposed of into sanitary sewers, treated and destroyed on-site, mailed through the United States Postal Service, or transported personally by small quantity generators directly to a disposal facility are not captured. The results presented in this Report include only data on medical waste that is incinerated on-site or shipped off-site using a transporter who has notified EPA. Therefore, the number of medical waste generators and the quantities reported here are subsets of the total number of medical waste generators located in the covered States, and the total quantities of medical waste generated in the covered States, respectively.

The activities that EPA will be taking to improve response rates and quantify the numbers of generators and quantities of waste not captured in the Medical Waste Reports are outlined in Section 4 below.

3. Summary of the Results from the First Reporting Period

a. Characterization of Medical Waste Generation

During the first six months of the medical waste program, approximately 48,000 tons of medical waste were produced by 16,400 generators in the covered States. The universe of medical waste generators who produced this waste is large and diverse, ranging from physicians' and dentists' offices to laboratories to hospitals. The number of medical waste generators and quantities of regulated medical waste generated in each of the covered States is presented in Exhibit 1 of Appendix 6.

The vast majority of the medical waste (about 90%) is produced by hospitals, which comprise only about 4% of the generators reported. Nearly 80% of the generators in the covered States are comprised of doctors, dentists, veterinarians, and clinics. This 80%, however, generates only a very small percentage (3%) of the medical waste that is generated in the covered States. The remaining generators are in many different industry sectors including laboratories, funeral homes, nursing homes, industrial facilities and others. Information on the number of generators and quantity of medical waste generated, by type of generator, is presented in Appendix 6, Exhibits 2 and 3.

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[29] As previously discussed, each transporter who notifies EPA must complete Transporter Reports and record every generator from whom he receives regulated medical waste. EPA estimates the quantity of medical waste generated and shipped off-site for treatment and disposal based on the Transporter Reports.

The information submitted in the transporter semi-annual reports also allows EPA to determine waste generation rates for generators who ship waste off-site, and the percentage of generators who generate less than 50 pounds per month (small quantity generators or SQGs). During the first reporting period, 86% of all generators produced less than 50 pounds per month of medical waste. Information on the number of generators who are SQGs for each generator type is presented in Appendix 6, Exhibit 2. This is especially interesting in light of the fact that the MWTA authorized, and EPA promulgated, regulations that included special provisions containing very limited regulatory relief for SQGs. Although SQGs must comply with all pre-transport regulations (segregating, packaging, storing, labelling and marking), the regulations allow SQGs to maintain logs in lieu of initiating a tracking form, or to personally transport waste (without obtaining an EPA identification number) to a disposal facility without using a tracking form. This information will also allow the Agency to determine the possible impacts of exempting small quantity generators from regulation or reducing their reporting requirements in the future.

The number of generators estimated from the Medical Waste Reports summarized in Appendix 6, Exhibit 2 is lower than the estimates provided in the First Interim Report to Congress. In the First Report, EPA estimated that there were roughly 60,000 generators, while in this Report EPA estimates that there are about 16,400 generators located in the five covered States. This estimate, however, includes only those generators who actually produce medical waste and either incinerate it on-site or ship it off-site using a transporter who has notified EPA. EPA believes, based on anecdotal information, that there are a substantial number of SQGs (10,000-15,000) that mail sharps off-site through the United States Postal Service (USPS). EPA currently is collecting information on this group of generators by working with companies marketing such services and will provide results in the Final Report.

In addition, estimates presented in the First Report were based on very limited information collected by Federal agencies and trade associations, and were premised on a number of conservative assumptions made by EPA. In fact, this number represents the estimated number of generators potentially affected by the regulations. Thus, the number of generators contained in the First Report included facilities that may not actually generate any medical waste (e.g., physicians whose practice involves largely consultation). Additionally, because the extent to which doctors or other health care providers practice in groups was not well documented in the available data sources, the First Report may have overestimated the number of generating entities (e.g., the number of physicians' offices). When comparing estimates specifically by generator category, the number of physicians, dentists, and veterinarians account for the major differences in estimates between this Report and the First Report.

b. Characterization of Medical Waste Management Practices

Most (98%) of the regulated medical waste generated during the first six months of the reporting period was incinerated. The remainder was either landfilled (1%) or treated and destroyed in a manner other than incineration (1%) (and then landfilled). Of the 48,000 tons[30] of regulated medical waste that was generated, 61% (29,600 tons) was shipped off-site to 82 disposal facilities, including 68 off-site incinerators, 8 landfills, and 6 treatment and/or destruction facilities. The remaining 39% (18,600 tons) was incinerated on-site by generators at approximately 250 facilities, primarily hospitals.[31] The number of each of the different types of treatment and disposal facilities is presented in Appendix 6, Exhibit 4, and the amount of medical waste that goes to each of the disposal alternatives, in each State, is presented in Appendix 6, Exhibit 5.

During the first six months of the demonstration program, 132 transporters hauled approximately 29,600 tons of regulated medical waste that was generated in the covered States to disposal facilities all over the country. The amount of waste that is shipped out-of-state for disposal varies considerably from State to State. For example, only 20% of the medical waste generated in Rhode Island is shipped out-of-state for disposal, while 59% of the medical waste generated in New York is shipped out-of-state for disposal. Information on the extent to which medical waste is shipped out-of-state for disposal, for each of the covered States, is presented in Appendix 6, Exhibit 6. Of all the regulated medical waste that is shipped off-site for disposal, only about 2% is treated (e.g., autoclaved) prior to shipment.

4. Future Agency Activities

In the next 12 months, EPA will be conducting a number of activities to characterize more fully medical waste generation, transportation, and disposal practices, and develop a "waste flow model" describing medical waste generation and management practices in the covered States and nationwide. The Agency will conduct the activities outlined below:

- Collect and summarize data obtained in the subsequent reporting periods;

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[30] There is a slight difference (<1%) between the quantity of regulated medical waste generated (Exhibit 2 of Appendix 6 (48,411 tons)) and the quantity disposed (Exhibit 5 of Appendix 6 (48,233)). The difference is due to inaccuracies in reporting of quantities by transporters.

[31] As discussed earlier in this Report, treatment and destruction are defined as performance standards. An example of treated and destroyed waste is medical waste that has gone through both an autoclave and a grinder.

- Work with the States and EPA Regional offices to supplement the information collected from the Medical Waste Reports (e.g., quantity information by waste class);

- Collect information, as needed, to refine assumptions underlying the Agency's medical waste flow model (e.g., estimate numbers of regulated generators and amounts of waste not being captured by the Medical Waste Reports);

- Collect information regarding the physical and chemical characteristics of the medical waste stream;

- Extrapolate the data collected in the covered States to develop nationwide estimates of the number of generators, transporters, and treatment and disposal facilities as well as the quantities of medical waste generated, transported, and treated and disposed;

- Use the data from the Medical Waste Reports to identify trends in medical waste generation, transportation, and treatment and disposal practices; and

- Continue education and enforcement activities to ensure that generators and transporters maintain required records and submit the required reports.

B. Update of Chapter 2, Health Hazard Assessment

1. Overview of Hazard Assessment Activities

In the First Interim Report to Congress, EPA proposed a methodology for assessing the potential health hazards of exposure to medical waste. According to this methodology, EPA intended to:

- evaluate the medical waste types listed in the MWTA to determine if they warrant reorganizing to facilitate the health assessment;

- identify pathogens that may be present in the various types of medical waste;

- designate qualitatively the "infectiousness" of each type of medical waste (e.g. infectious, potentially infectious, non-infectious);

- quantify the pathogens in each type of medical waste; and

- translate these findings with respect to potential health hazards.

EPA further proposed to use the epidemiological findings in the ATSDR Report to Congress to support its determinations on the health hazards of medical waste[32]. Because ATSDR has limited its report to HIV and HBV transmission and injuries, EPA will use ATSDR's findings to support any conclusions pertaining to the potential transmission of these two viruses from exposure to medical waste.

2. Review of Activities Undertaken

This update chronicles EPA's activities regarding the health hazard assessment since the First Interim Report. Because the health assessment has not yet been completed, specific details of findings will not be available until the Final Report to Congress.

Upon re-examining the types of medical waste enumerated in the Act, EPA determined they were suitable for performing a health assessment. In some cases, however, subcategories within types of waste were created to further assist in the health assessment. A comprehensive list of medical waste items has been developed. This list led to the delineation of three additional types of waste (for a total of 13 types) for purposes of the health assessment.

In performing the second phase, pathogen identification, EPA is examining research facility wastes and health care facility wastes separately. Although the wastes from research facilities are quite similar to those from health care facilities, the pathogens in research facilities tend to be in greater concentrations, are known, and CDC guidelines[33] govern their handling and disposal.

In health care facility wastes, the pathogens present are largely unknown. Using the CDC's Guideline for Isolation Precautions in Hospitals, EPA derived a list of approximately 70 classes of pathogenic bacteria, viruses, fungi, and protozoa that may be present in health care facilities. This list did not account for such factors as survivability outside the host. Information about reservoirs (i.e., where infectious agents normally live and reproduce, such as in the human body or the soil) and sources (i.e., object or person from which an infectious agent passes immediately to a host) of the pathogens, the fluids, excretions, secretions, and body tissues that can contain the various pathogens and mode of transmission were used to link pathogens subjectively to types of medical waste. Because many pathogens die rapidly outside their hosts, EPA developed a methodology for excluding such pathogens from continued analysis. Further, many pathogens were excluded if they had low incidence rates and are the target of required immunization programs, making it very unlikely that they will be found in the waste. It is interesting to note that the pathogens not excluded by the study methodology are the same as those reported in published studies in which samples of medical waste were analyzed for pathogen content.

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[32] Section 11009 of the MWTA (42 U.S.C. § 6992h) requires ATSDR to prepare a Report to Congress on the health effects of medical waste.

[33] Centers for Disease Control, Classification of Etiologic Agents on the Basis of Hazard (July, 1974).

The pathogens that were not excluded are being analyzed with respect to the factors necessary for disease transmission. This additional analysis should qualitatively elucidate those wastes warranting concern for public exposure. Information on infective dose and survivability has been and continues to be collected for the pathogens of concern. While some information on infective dose is readily available, it primarily pertains to the enteric bacteria. Information collected thus far (for bacteria and viruses) on survivability show rapid die-off of pathogens exposed to various environmental conditions.

Epidemiological data searches (other than those performed by ATSDR) for disease transmission from exposure to medical waste either in the workplace or in the community have been conducted. Unfortunately, epidemiological information is scarce and tends to focus on occupational exposures such as needle-stick injuries.

Presently, work is also being performed to develop exposure scenarios. This work is being performed in conjunction with the work identifying handling methods for medical waste to determine how the public may come in contact with the waste.

C. Update of Chapter 3, Estimated Costs of the Demonstration Program and Improper Management of Medical Waste

Cost-related data is not yet available for analysis. Nevertheless, this update sets forth a list of current Agency efforts and a forecast of the cost and benefit analysis to be included in the Final Report.

- The Agency will refine its cost analysis of the interim final rule to incorporate data on generators, transporters and TDD facilities and waste volume.

- The Agency will seek information on changes in medical waste disposal and transporter costs resulting from the tracking program. It is not yet known whether the Agency will be able to collect more than anecdotal information.

- The Agency will collect and discuss data concerning state and local efforts to assess the costs to local communities from improperly managed medical waste resulting in beach wash-ups.

- To the extent possible, the Agency will include other impacts of improperly managed medical waste (such as impacts to human health and the environment). At this time, EPA believes that it is unlikely that data will be available to conduct any form of quantified analysis.

D. Update of Chapter 4, Demonstration Program Objectives and Evaluation

Since passage of the MWTA, EPA and the covered States have established a coordinated regulatory program for the tracking and management of medical waste. Although the Agency believes that it is premature to fully evaluate the success of the program, it believes that the regulations are successful in controlling the management (e.g., packaging, labelling, storage, etc.) and tracking of waste that is shipped off-site for disposal in the States it covers. EPA also believes that the program has to some extent been successful in addressing its broader goals of increasing public awareness and encouraging sound waste management practices by those excluded from the regulations by statute, but contributing to the problem (e.g., household waste). Section IV of this Report includes a more thorough discussion of the direct and indirect impacts of the program.

In the next 12 months of the demonstration program, EPA will continue to monitor the program and collect information that will allow it to evaluate more fully the success of program in meeting the objectives of the MWTA and Congress. Information will be collected on the extent to which the regulations were complied with; the appropriateness of the scope of the wastes that are regulated; the functioning of the tracking requirements; the appropriateness of the management standards; and on the changes in waste management practices that result from the program.

In the Final Report, EPA will also expand on information presented in the First Report regarding alternative methods for tracking wastes, and will evaluate the advantages and disadvantages of extending such requirements to rural areas and small quantity generators. These discussions will be based on the information collection efforts described in Section V.A. of this report.

E. Update of Chapter 5, Medical Waste Handling Methods

EPA is analyzing waste handling methods for inclusion in the Final Report to Congress. This analysis will include medical waste handling method flow charts for certain generator groups. The flow charts will be reviewed by at least two persons or groups familiar with waste handling practices (e.g., representatives of trade associations or facilities). The charts will compare waste handling methods in covered States to waste handling methods in noncovered States. The Agency also will prepare a report that summarizes and integrates the information from these generator groups.

F. Update of Chapters 6 & 7; Medical Waste Treatment Method and Medical Waste Treatment Effectiveness

1. Introduction

As an initial step to evaluating medical waste treatment technologies, EPA has conducted an overall assessment of available treatment technologies which includes:

- what types of waste can be treated by a specific technology;
- what operating conditions influence the treatment method;
- what residuals are produced from the treatment method; and
- what studies have been conducted on the effectiveness of the treatment method and on-going research initiatives.

This initial assessment was presented in the First Interim Report.

2. Current Activities

Current activities to thoroughly evaluate treatment technologies have focused on the most commonly used methods (prior to ultimate land disposal or discharge to sewers). Each of the most commonly used treatment technologies will be tested, if possible, to determine its ability to render medical waste non-infectious or less infectious and unrecognizable. Additionally, EPA will be examining what technological parameters influence the effectiveness of that treatment technology (e.g., quality assurance, operator training, equipment maintenance). Considering the extreme microbial variation within the overall medical waste stream, EPA will be utilizing indicator microorganisms to study the effectiveness of specific treatment technologies. This approach will be taken because there are variations in waste streams from different types of generators; variations in waste streams generated from different locations with the facility; and inadequate information regarding the actual microbial content of medical waste. Moreover, indicator organisms are representative of the most resistant type of organism for that particular treatment technology.

These studies also will be used to help identify possible routes of transmission for microorganisms during the treatment process and any additional treatment and disposal activities required for each technology to ensure proper and final waste disposition.

As noted in the First Interim Report to Congress, the MWTA listed several procedures as treatment which do not influence the biological composition of the medical waste, but instead address the appearance of the waste (i.e. grinding, shredding and compaction). Some treatment technologies utilize one or more of these procedures in conjunction with an actual biological treatment method to either make the waste unrecognizable or significantly reduce the volume of waste to be disposed of.

Additionally, as a result of the MWTA many new treatment methods are emerging, primarily for the small quantity generator. EPA is in the process of developing criteria to evaluate these new methods and determining if the treatment method meets the intent and definition of "treatment" and/or "destruction" found in the interim final rule.

G. Update on Chapter 8, Existing State and Local Requirements

1. Overview

The Agency is carrying out at least two projects related to State and local requirements that will be made part of the Final Report, including:

- analysis of state regulations; and
- assessment of preventive action taken by covered States.

These projects are discussed in detail below.

2. Analyzing State Medical Waste Regulations

EPA is researching the existing medical waste requirements for the five covered States in order to update their current medical waste regulations. Additionally, the Agency will study existing and planned medical waste regulations in the seven States that "opted out" of the demonstration program. This information will be analyzed and compared to the major elements of the medical waste programs in the covered States. The objective of this analysis is:

- to determine if the States that opted out have programs, and if so, what are the major differences between the programs; and
- to support the evaluation of the effectiveness of the demonstration program by determining whether problems experienced by the States that opted out could have been avoided if they had remained in the program.

The Agency is compiling a list of the most important factors for successful medical waste management programs (e.g., tracking, packaging, disposal methods, comprehensiveness of medical waste definition) and developing a table or matrix to summarize such information. In the process of obtaining information about State programs, EPA will update its state contact list.

The key areas of information collection are:

- nature of the medical waste program (regulatory or nonregulatory);
- treatment of home health care sector (inclusion or exclusion); and
- scope of the programs.

3. Assessing State Preventive Actions

The Agency will research the specific steps (in addition to promulgation of medical waste regulations) that the covered States have taken to control the sources of medical waste. In addition, information will be collected in the covered States concerning the number of wash-ups, beach closings, and the amounts and types of items.

H. Update to Chapter 9, Regulatory Options For a National Program

The Agency recognizes that many states have regulations which address medical waste. Thus, EPA has decided to evaluate and develop "Model State Guidelines for Medical Waste Management" through a cooperative agreement with an independent non-profit organization. The recipient of the cooperative agreement will be a national organization, able to obtain information from various state regulatory agencies, and with the technical expertise to develop guidance for waste management activities. The recipient will be asked to address the following:

- developing a medical/infectious waste definition;
- developing approaches for medical waste handling, treatment, transportation, and disposal;
- make recommendations on management of home-health care waste; and
- developing criteria for managing medical waste mixed with other waste streams, such as medical waste mixed with radioactive waste and medical waste mixed with hazardous waste.

The results of this study will be incorporated into the Final Report to Congress.

I. Chapter 10, Appropriateness of Penalties

The Agency is currently collecting information on the numbers and types of inspections and enforcement actions, and following up on actions taken to ensure compliance at problem facilities, and to evaluate the appropriateness of penalties provided by the MWTA. EPA is also meeting periodically with the States to coordinate programs and identify and discuss issues, including the appropriateness of penalties provided by the Act. Because the program has been in place for less than a year, however, the Agency believes that it is premature to make such a determination in this Report.

J. Chapter 11, Home Health Care and Small Quantity Generator Waste

In the First Report, EPA estimated the types and quantities of health care wastes generated in households, discussed the effect of excluding households and small quantity generators from the regulations, and outlined its strategy for public education on the proper management and disposal of home health care waste.

Since that time, EPA has been active in two general areas. First, using information submitted by transporters and operators of on-site incinerators, EPA has refined its estimate of the numbers and types of generators, including the percentage of generators that are small quantity generators (see also section V.A.). Second, EPA has developed a brochure in conjunction with approximately a dozen trade associations to promote the safe disposal of home health care wastes. EPA will continue these initiatives and report more fully on the effect of excluding households and small quantity generators from regulations, and on additional education and outreach efforts in the Final Report.

K. Chapter 12, Medical Waste Reuse, Recycling and Reduction

Since the First Interim Report, the Agency has collected no additional information regarding the reuse or reduction in volume of medical waste. The Agency has, however, initiated a study to assess (among other things) the potential for waste minimization. The study has two primary objectives. The first is to identify practices or techniques that can be used to reduce the volume of waste that is generated. The second is to identify techniques that can be adopted to reduce the potential threat posed by medical waste. This will include identifying the sources of toxic constituents (e.g., heavy metals) in the waste stream, and suggesting product reformulation or waste component segregation to avoid having toxics enter the waste stream, or to avoid having materials managed in a environmentally harmful way. Results of this initiative will be summarized in the Final Report.

APPENDICES

Appendix 1 - Syringe related information - EPA Harbor Studies program
Appendix 2 - Enforcement Information
Appendix 3 - EPA Instructional Booklets
Appendix 4 - Home Health Care Disposal Tip Pamphlet
Appendix 5 - Grant Proposals & Descriptions
Appendix 6 - Information Charts and Materials from the First Reporting Period

APPENDIX 1

TABLE 1.

SUMMARY OF CONDITION OF SYRINGES RECEIVED ON FEBRUARY 1, 1990 FOUND DURING EPA HARBOR STUDIES PROGRAM

Each sample was packaged in a ziploc bag. Some samples contained more than one item suitable for analysis and were numbered accordingly. The descriptions below are of the contents of each ziploc bag. One bullet indicates which samples suitable for analysis. Two bullets mark the samples which were sent to the laboratory for analysis.

SAMPLE NUMBER		SAMPLE DESCRIPTION
AAK-441		• One ziploc containing one 1 cc syringe with plunger completely depressed. Needle is capped, plunger is uncapped.
AAK-480		One ziploc containing:
	(1)	• One 1 cc syringe with needle uncapped; plunger is completely depressed and uncapped.
	(2)	• One 1 cc syringe with both ends capped and the plunger completely depressed; tape is wrapped around the plunger cap.
	(3)	•• One 1 cc syringe with the needle capped and the plunger half-way depressed.
	(4)	• One 1 cc syringe with no caps, no needle and the plunger completely depressed.
AAK-416		•• One syringe; the needle cap is approximately 1-½" long, but the needle is approximately ½" in length; the plunger is uncapped and mostly depressed.
AAK-511		One ziploc containing:
	(1)	• One 1 cc syringe with both ends capped.
	(2)	One small ziploc.
AAK-509		One ziploc containing:
	(1)	• One 1 cc syringe with needle capped and the plunger uncapped and completely depressed.
	(2)	• One 1 cc syringe with the needle capped and the plunger uncapped and completely depressed.

	(3)	• One 1 cc syringe with the needle capped and the plunger uncapped and completely depressed.
	(4)	• One 1 cc syringe with both ends capped.
	(5)	• One 1 cc syringe with no caps and no needle, the plunger is completely depressed.
	(6)	Miscellaneous: two needle caps
AAK-510		One ziploc containing:
	(1)	• One plastic bag containing one 1 cc syringe with the needle capped and the plunger uncapped and completely depressed; the syringe appears to be coated in yellow paint with hair emerging from the plunger-end of the barrel
	(2)	Miscellaneous: syringe cap.
AAK-289A2		• One 1 cc syringe with a capped needle and uncapped plunger; the needle is bent so as to stick through the cap.
AAK-257		• One syringe with the needle capped (the cap is curved and tapered), and plunger depressed.
AAK-287	(1)	• One 1 cc syringe capped at both ends.
	(2)	• One 1 cc syringe capped at both ends.
	(3)	One syringe barrel with no caps, needle or plunger.
AAL-228		• One 1 cc syringe with a capped needle (the cap is punctured), the plunger depressed and uncapped, and black solids in the barrel.
AAL-226		• One 1 cc syringe with a capped needle (cap is punctured), the plunger depressed and uncapped.
AAK-190		One ziploc containing:
	(1)	• One capped needle (1 ¼") with similar bore size to that used in hematology.
	(2)	• One 1 cc syringe with no needle, no caps and the plunger broken and a quarter depressed.
AAK-535		• One ziploc containing one 1 cc syringe with both ends uncapped, a bent needle, and the rubber end of the plunger only, remaining in the barrel; contains a clear fluid.

AAK-168		One ziploc containing one syringe barrel (no needle attached), one syringe plunger and one syringe cap.
AAK-191	(1)	One broken 1 cc syringes with a plunger and a bent needle (neither ends capped).
AAL-232	(1)	• One 1 cc syringe with both ends capped.
	(2)	• One 1 cc syringe with both ends capped.
	(3)	• One 1 cc syringe with the needle capped (the cap is larger than typical tapered, but the needle is a typical ½" length), and the plunger partially depressed.
	(4)	• One 1 cc syringe with no needle, plunger completely depressed and neither end capped.
	(5)	• One 1 cc syringe with a capped needle which is bent back inside barrel and an uncapped plunger almost completely depressed.
	(6)	• One 1 cc syringe with a capped needle and an uncapped plunger completely depressed.
	(7)	Miscellaneous: 2 syringe caps.
AAK-293		• One 1 cc syringe with a bent needle, the plunger completely depressed and both ends uncapped.
AAL-230	(1)	•• One 1 cc syringe with the barrel half filled with red-brown substance (apparently blood), the uncapped needle is bent (approximately 20°), plunger is half-way depressed and uncapped.
	(2)	• One 1 cc syringe capped a both ends, although the needle is bent back outside the cap.
	(3)	• One 1 cc syringe with an uncapped bent needle (approximately 110°) and an uncapped plunger completely depressed.
	(4)	Miscellaneous: plunger and 2 syringe caps.
AAK-262		2 syringe caps.

TABLE 2.

SAMPLE IDENTIFICATION

AML Account Number: 15011

SAMPLE NUMBER		AML NUMBER	RESULTS
0	AAL-230(1)	09421272/0	Positive: insulin, cocaine
1	AAK-416	09421275/0	Negative
2	AAK-480(3)	09421273/0	Positive: cocaine, lidocaine
3	AAL-232(3)	09421272/0	Positive: Insulin
4	AAK-191(1)	09421271/0	Negative

REMAINING SAMPLES:

AAK-191(1)
AAK-190(2)
AAK-190(3)
AAK-257
AAK-287(1)
AAK-287(2)
AAK-289A2
AAK-293
AAK-441
AAK-480(1)
AAK-480(2)
AAK-480(4)
AAK-509(1)
AAK-509(2)
AAK-509(3)
AAK-509(4)
AAK-509(5)
AAK-510(1)
AAK-510(2)
AAK-511(1)
AAK-535
AAL-226
AAL-228
AAL-230(2)
AAL-230(3)
AAL-232(1)
AAL-232(2)
AAL-232(4)
AAL-232(5)
AAL-232(6)

APPENDIX 2

ENFORCEMENT INFORMATION

TABLE 1

INSPECTIONS BY EPA*

State	Number of Facilities Inspected
New York	249
New Jersey	213
Puerto Rico	28
North Carolina	1
Pennsylvania	1
South Carolina	1
Connecticut and Rhode Island (combined)	19
TOTAL	512

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[*] This table does not include inspections conducted by State agencies.

TABLE 2

TYPES OF ENFORCEMENT ACTIONS BY EPA

Type of Action	Number of Facilities
Inspections	512
Warning Letters or Notices of Violations	257
Administrative Actions	11*

* One Administrative Action is currently in draft form.

TABLE 3

PENALTIES ASSESSED BY EPA

EPA Region I	$ 67,000
EPA Region II	$625,500
TOTAL	$692,500

APPENDIX 3

EPA Instructional Booklets

United States
Environmental Protection
Agency

EPA/530-SW-89-020
May 1989

Office of Solid Waste

EPA

Tracking Medical Wastes

Printed on recycled paper.

The summer of 1988 will be remembered for the closing of East Coast beaches after the discovery of medical wastes along the shore. In other places, syringes and needles have been discovered in and around dumpsters, gutters, and other public areas. Such alarming incidents are a reminder that medical wastes have too often been mismanaged. The public has expressed concern over the aesthetic blight and the potential threat these wastes pose to their health and the environment. In response to public concerns, the Environmental Protection Agency (EPA) and many states are developing programs to control the disposal of medical wastes.

Congress Acts

In the fall of 1988, Congress passed *The Medical Waste Tracking Act*. The law calls for a two-year demonstration tracking program for medical wastes. The program is to serve as a first step in controlling the irresponsible disposal of medical wastes. In enacting the law, Congress recognized that medical wastes require special handling and disposal and that experience gained from a pilot program would serve as a guide to their proper management. Moreover, Congress anticipated that a regionwide demonstration program would provide a realistic test for determining the need for a national program to track medical wastes.

***The Medical Waste Tracking Act* amends the *Resource Conservation and Recovery Act* (RCRA) by adding Subtitle J. It defines medical waste as " . . . any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. . . ."**

The Medical Waste Tracking Act requires EPA to establish a two-year demonstration program in New York, New Jersey, Connecticut, and the states bordering the Great Lakes. The program is to provide generators of medical wastes with a uniform method of tracking these wastes to help ensure that the wastes are disposed of properly. EPA is also directed to set standards for safely separating, packaging, and labeling these wastes before they are shipped to authorized treatment or disposal facilities.

Under the legislation, the States of New York, New Jersey, and Connecticut could choose to either participate in the demonstration program or implement their own no-less-stringent medical waste tracking programs. The Great Lakes States could choose not to participate at all. Any other state wishing to participate could petition EPA to do so. A state governor could elect to participate or not, but had to notify EPA within 30 days after EPA set up the demonstration program.

EPA Sets Up A Demonstration Program

EPA is required, as part of the law, to publish a regulation establishing the medical waste demonstration program by May 1989. EPA issued the rule in March 1989 to give states enough time to ensure that a demonstration program would be in place by summer. New York, New Jersey, and Connecticut have been joined by Rhode Island and Puerto Rico as participants in the two-year federal demonstration program.

In developing the regulation, EPA worked cooperatively with a variety of interested parties such as affected states, other federal agencies, the health care community, the waste management industry, and environmental groups. EPA considered the concerns of these groups as it developed the regulation.

In addition, EPA created an in-house task force to guide activities related to medical waste management. To help ensure the safe disposal of these wastes, EPA will continue to work with states, Congress, industry and environmental groups, and the medical community, including physicians, hospitals, nursing and funeral homes, and veterinarians. Other communication with the public is being planned as well.

The regulation establishing the pilot program is an interim final rule, which takes effect in early summer of 1989. EPA will consider public comments that were received during the public comment period, as well as lessons learned from actual program operations, as the Agency refines the medical waste tracking program.

What This Demonstration Program Will Accomplish

For the first time, certain medical wastes will be regulated by federal law and tracked in a special way—not as hazardous waste or general trash. The program is an important step in preventing public exposure to medical wastes. It will assure that regulated medical wastes are properly packaged and separated from general refuse to protect workers, the public, and the environment from possible risk. Since many of these wastes no longer will be thrown into the trash, EPA expects that less medical waste will wash up on beaches and float on waterways. The new program will also set up a tracking system to identify and increase the accountability of those who generate, transport, and dispose of these wastes.

EPA, in cooperation with participating states, will review and evaluate the demonstration program. As required by the law, the Agency will report to Congress on program accomplishments, limitations, and any problems that occur during the two years. In this way, everyone can learn what works and what does not work to control this difficult problem.

What The Program Does Not Address

The demonstration program will control institutional and commercial sources of medical waste in the participating states. But some sources, such as diabetics in private households, cannot be controlled by this program. However, these and other individuals can take responsibility for protecting their families and neighbors by safely disposing of their used needles and other medical wastes. For example, sharp implements can be put into boxes especially designed for the disposal of sharps or sealed in a rigid container, such as a coffee can. Other medical wastes can be securely tied in a heavy plastic bag. The wastes can then be taken to a medical facility for disposal. If this is not possible, the wastes can be placed in a garbage can with a tightly fitting lid. Nurses and other home health care professionals can also handle home wastes in this way and inform their patients about these safe methods for disposing of medical wastes. EPA will soon provide more specific guidance on proper home medical waste disposal.

Also not addressed by the law are people who litter or who use illegal drugs. Medical wastes carelessly tossed into streets or open trash cans can land in city storm sewers and eventually find their way to rivers and streams. Drug enforcement and *Clean Water Act* programs usually address such problems. Citizen cleanup and litter control projects also work to eliminate the flagrant dumping of waste.

Wastes Covered By The EPA Rule

The EPA rule concerns only regulated medical wastes generated in participating states. Specifically, the following medical wastes—and other wastes that have been mixed with them—are regulated:

- **Cultures and stocks of infectious agents**
- **Pathological wastes**
- **Human blood and blood products**
- **Sharp implements—used and unused**
- **Contaminated animal waste**
- **Isolation waste from patients with highly communicable diseases**

Pre-transporting Requirements

Before medical wastes leave the site where they are produced, generators must take certain precautions to protect workers, handlers, and the public from exposure to these materials. First, generators must separate them from general trash. Then, to ensure that wastes are packed securely and will not leak, the regulation specifies that medical wastes are to be packaged in rigid, leak-resistant containers. Sharps, such as needles and scalpels with their residual fluids, are separated from other medical wastes and packed in puncture-resistant containers. Uncontained fluids are poured into tightly-stoppered and break-resistant containers. Other medical wastes may be placed together in a package that is rigid and resistant to leaks.

The regulation is designed to prevent packages from being damaged during shipping and handling, thus preventing accidental contact with workers or the public. Therefore, a rigid outer container, or secondary packaging, is generally required during shipping. Specific standards also apply to regulated wastes that are stored during preparation for shipping and disposal.

When secondary packages, such as bins, buckets, and boxes, are reused, they must be cleaned thoroughly. Primary packages—inner containers—are not reusable and are handled as medical wastes.

Finally, generators must label and mark packages clearly, identifying the content, the generator, and the transporter. As these wastes move through the disposal process, they are carefully tracked.

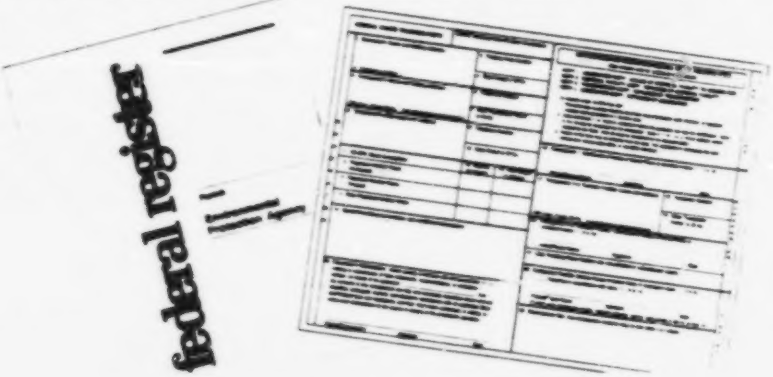
Tracking Medical Wastes

When a generator finishes preparing a package of medical wastes bound for treatment or disposal at another site, the generator fills out a tracking form. Only transporters who have registered with EPA may carry these wastes from the generator to the disposer. In the case of a generator of small quantities of medical wastes, a log shows who is carrying the wastes and where the wastes are going, and a tracking form is initiated by the transporter.

As the wastes travel to their final disposal, the tracking form goes with them. Each transporter and owner or operator of a treatment or disposal facility signs and keeps one copy of the tracking form. The generator receives the final copy, indicating that the wastes were received at an authorized disposal facility. The operations at the facility may be controlled by other federal, state, and local laws and regulations.

More Information

For a copy of the "Standards for the Tracking and Management of Medical Waste" interim final rule and for up-to-date information concerning states' participation and contacts, call the RCRA Hotline at (800) 424-9346 or 382-3000 in Washington, D.C.



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United States
Environmental Protection
Agency

Solid Waste and
Emergency Response
(OS-305)

EPA/530-SW-89-021
September 1989

EPA

Managing and Tracking Medical Wastes

A Guide to the Federal Program for Generators

Printed on recycled paper.

Introduction

In response to the growing public concern over mismanagement of medical wastes, Congress enacted the *Medical Waste Tracking Act*. The Act charges the Environmental Protection Agency with responsibility for implementing a two-year demonstration medical waste tracking program that will help determine the best medical waste management procedures for the future. The program's goal is to find an effective means to ensure that regulated medical wastes get from their point of generation to their point of disposal.

Generators of regulated medical wastes will be part of the new demonstration tracking program in the States of Connecticut, New Jersey, New York, and Rhode Island, and the Commonwealth of Puerto Rico. Transporters and facilities that store, treat, destroy, and dispose of these wastes will also be part of the program.

This guide offers general information about the tracking program (Section 1) and specific instructions for regulated medical waste generators (Section 2). Section 2 includes requirements for generators of more than 50 pounds a month, such as hospitals, and special requirements for those producing less, such as physicians, dentists, and veterinarians. Separate guides in this series are provided for transporters and for facilities that treat, destroy, and dispose of regulated medical wastes.

This guide describes the federal program only. It is designed to help generators comply with the program. For more complete information, generators should refer to "Standards for the Tracking and Management of Medical Waste," interim final rule (40 CFR Part 259). In addition, states participating in the program have their own rules for managing medical waste. The Appendix lists addresses and phone numbers for offices in participating states and for EPA Regional Offices.

For additional copies of *Managing and Tracking Medical Wastes* or a copy of 40 CFR Part 259, call the RCRA Hotline at (800) 424-9346 or, in Washington, D.C., 382-3000.

The cooperation of all participants in the management of regulated medical waste will assure the success of this important demonstration program and reduce public exposure to the waste.

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Section 1: The Medical Waste Tracking Program

In response to public concern over the mismanagement of medical wastes, the *Medical Waste Tracking Act* was enacted in the fall of 1988. The law directs the Environmental Protection Agency (EPA) to establish a two-year demonstration program for tracking medical wastes.

Under this law, EPA has issued regulations entitled "Standards for the Tracking and Management of Medical Waste" (40 CFR Part 259). The regulations list the medical wastes to be tracked and cover standards for separating, packaging, and labeling medical wastes before sending them for treatment or disposal. The results of the demonstration program are intended to help determine whether such a program should be extended nationwide.

> **The *Medical Waste Tracking Act* amends the *Resource Conservation and Recovery Act* (RCRA) by adding Subtitle J. It defines medical waste as " . . . any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. . . . "**

Participating in the demonstration program are the States of Connecticut, New Jersey, New York, and Rhode Island, and the Commonwealth of Puerto Rico. The regulation is an interim final rule. It will be in effect for two years, until June 22, 1991. In Connecticut, New Jersey, and New York, the program is effective beginning June 22, 1989; in Rhode Island and the Commonwealth of Puerto Rico, the program is effective beginning July 24, 1989.

The demonstration program involves **only** regulated medical wastes **generated in one of the states** participating in the program, even when these wastes leave the state. The program sets up a system for tracking the waste from the generator to the disposal site. A tracking form that accompanies this waste is signed and a copy is retained by a representative of the waste generator and each transporter, transfer station, and treatment, destruction, and disposal facility handling it. When the final disposer—the destination facility—accepts the waste, a copy of the signed tracking form is returned to the generator. In this way the generator is assured that the waste was received for disposal. The tracking system includes "exception" and "discrepancy" reporting to alert EPA and the states if wastes are not being handled properly.

To minimize contact with regulated medical wastes by workers, handlers, and the public, the program includes specific requirements for segregating, packaging, labeling, marking, and storing medical wastes before they are shipped to another site for treatment, destruction, or disposal. Other requirements include recordkeeping, reporting, and enforcement. EPA will evaluate the success of the program and report the results to Congress.

Waste Managers Participation

This booklet is intended to help generators comply with the federal rules in the participating states. Generators of regulated medical waste in these states must also follow rules required by the individual states. Generators should check with their state officials for clarification of state rules. While participating states use the same basic tracking form as EPA's, some states might regulate more wastes or require special permits or licenses. In addition, individual states might not recognize some of the special exceptions allowed under EPA rules. Participating states are authorized to enforce this program.

The demonstration program also includes owners and operators of treatment, destruction, and disposal facilities that manage waste generated in a participating state, even if their facilities are located in a nonparticipating state. Similarly, the program includes transporters carrying regulated medical waste from a participating state, even if the waste is then taken to a nonparticipating state. The program includes vessels and transporters that take medical wastes to shore from ships docked in participating states. Federal facilities generating regulated medical waste in participating states are also covered under this program.

Regulated Medical Wastes

Medical wastes affected by the pilot program include

- cultures and stocks of infectious agents.
- human blood and blood products.
- human pathological wastes, including those from surgery and autopsy.
- contaminated animal carcasses from medical research.
- wastes from patients isolated with highly communicable diseases.
- all used sharp implements, such as needles and scalpels, and certain unused sharps.

These regulated medical wastes fall into two categories: untreated or treated. The Glossary provides detailed descriptions of these medical wastes.

The demonstration program focuses on wastes that historically have been improperly managed and are most likely to pose a substantial threat to human health and the environment. However, any additional waste that a health care professional believes may pose a risk should be handled as a regulated medical waste.

Mixtures of regulated medical waste and general trash are regulated as medical waste. Mixtures of regulated medical waste and hazardous waste are usually regulated as hazardous waste. However, if medical waste is mixed with hazardous waste, which falls under the small quantity hazardous waste exemption, then the waste mixture must be tracked as medical waste under this program.

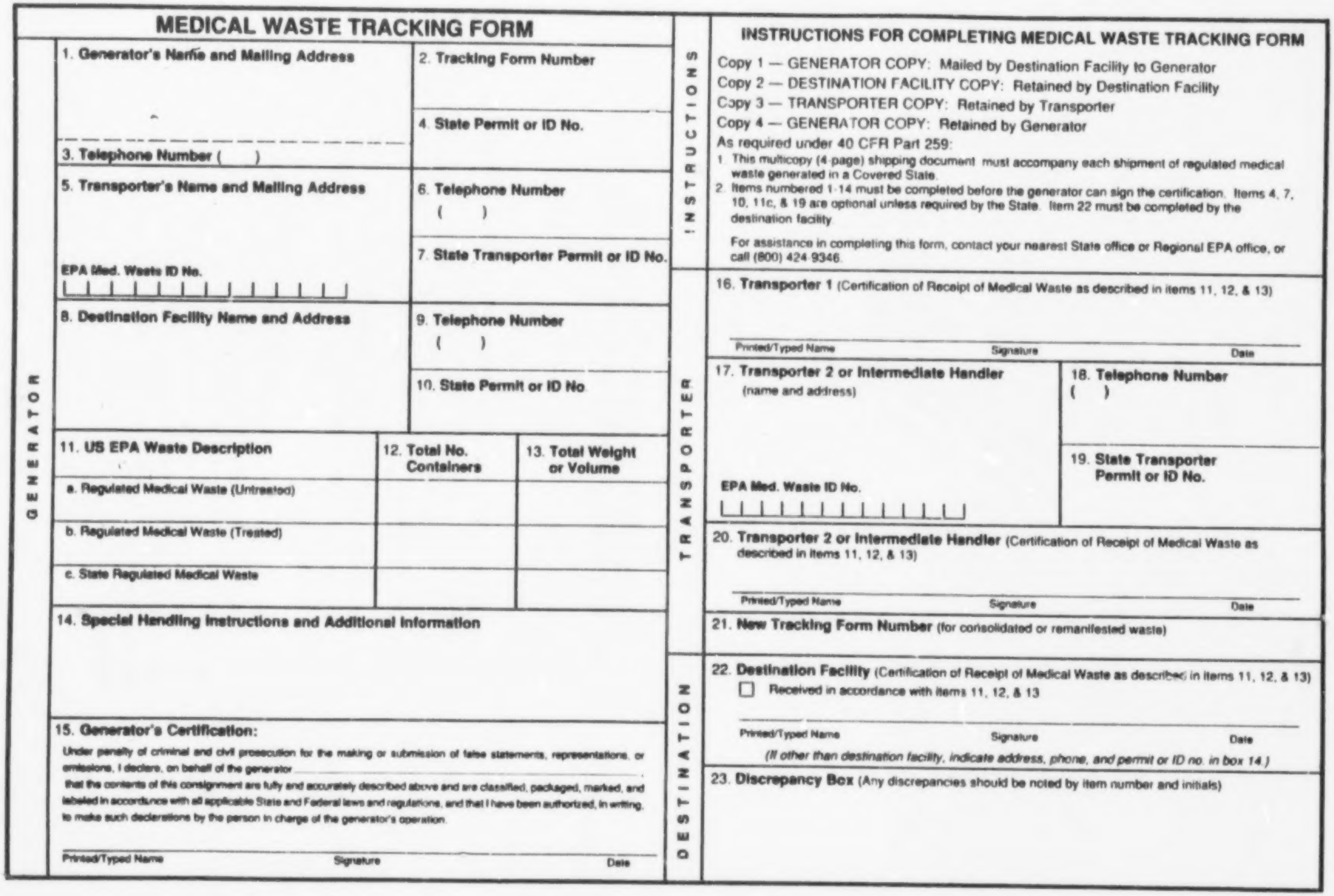
Pre-transporting Procedures

Regulated medical wastes that are to be transported to an off-site facility for treatment or disposal must be properly prepared for shipping. First, the wastes must be separated from general trash, and then sharp items, fluids, and other medical wastes must be separated from each other. They are then packaged to prevent tearing, breaking, or leaking during shipping and handling.

Packages are to be labeled and marked to identify the contents of the package and the generator and transporter of the waste. In addition, stored wastes must be maintained to prevent them from coming into contact with workers or the public.

Tracking Regulated Medical Wastes

At the core of the medical waste demonstration tracking system is a Medical Waste Tracking Form (see Figure 1). This form must accompany each off-site shipment that weighs 50 pounds or more. Shipments from generators of less than 50 pounds a month may be combined onto one tracking form by the transporter. Generators, transporters, and treatment, destruction, and disposal facilities are responsible for filling in, forwarding, and retaining a copy of this form for their records. Figure 2 illustrates how the medical waste tracking system works.



MEDICAL WASTE TRACKING FORM

GENERATOR

1. Generator's Name and Mailing Address

2. Tracking Form Number

3. Telephone Number (   )

4. State Permit or ID No.

5. Transporter's Name and Mailing Address

6. Telephone Number (   )

EPA Med. Waste ID No.

7. State Transporter Permit or ID No.

8. Destination Facility Name and Address

9. Telephone Number (   )

10. State Permit or ID No

11. US EPA Waste Description	**12. Total No. Containers**	**13. Total Weight or Volume**
a. Regulated Medical Waste (Untreated)		
b. Regulated Medical Waste (Treated)		
c. State Regulated Medical Waste		

14. Special Handling Instructions and Additional Information

15. Generator's Certification:

Under penalty of criminal and civil prosecution for the making or submission of false statements, representations, or omissions, I declare, on behalf of the generator ______________________, that the contents of this consignment are fully and accurately described above and are classified, packaged, marked, and labeled in accordance with all applicable State and Federal laws and regulations, and that I have been authorized, in writing, to make such declarations by the person in charge of the generator's operation.

Printed/Typed Name   Signature   Date

INSTRUCTIONS

INSTRUCTIONS FOR COMPLETING MEDICAL WASTE TRACKING FORM

Copy 1 — GENERATOR COPY: Mailed by Destination Facility to Generator
Copy 2 — DESTINATION FACILITY COPY: Retained by Destination Facility
Copy 3 — TRANSPORTER COPY: Retained by Transporter
Copy 4 — GENERATOR COPY: Retained by Generator

As required under 40 CFR Part 259:

1. This multicopy (4-page) shipping document must accompany each shipment of regulated medical waste generated in a Covered State.
2. Items numbered 1-14 must be completed before the generator can sign the certification. Items 4, 7, 10, 11c, & 19 are optional unless required by the State. Item 22 must be completed by the destination facility.

For assistance in completing this form, contact your nearest State office or Regional EPA office, or call (800) 424-9346.

TRANSPORTER

16. Transporter 1 (Certification of Receipt of Medical Waste as described in items 11, 12, & 13)

Printed/Typed Name   Signature   Date

17. Transporter 2 or Intermediate Handler
(name and address)

EPA Med. Waste ID No.

18. Telephone Number (   )

19. State Transporter Permit or ID No.

20. Transporter 2 or Intermediate Handler (Certification of Receipt of Medical Waste as described in items 11, 12, & 13)

Printed/Typed Name   Signature   Date

21. New Tracking Form Number (for consolidated or remanifested waste)

DESTINATION

22. Destination Facility (Certification of Receipt of Medical Waste as described in items 11, 12, & 13)

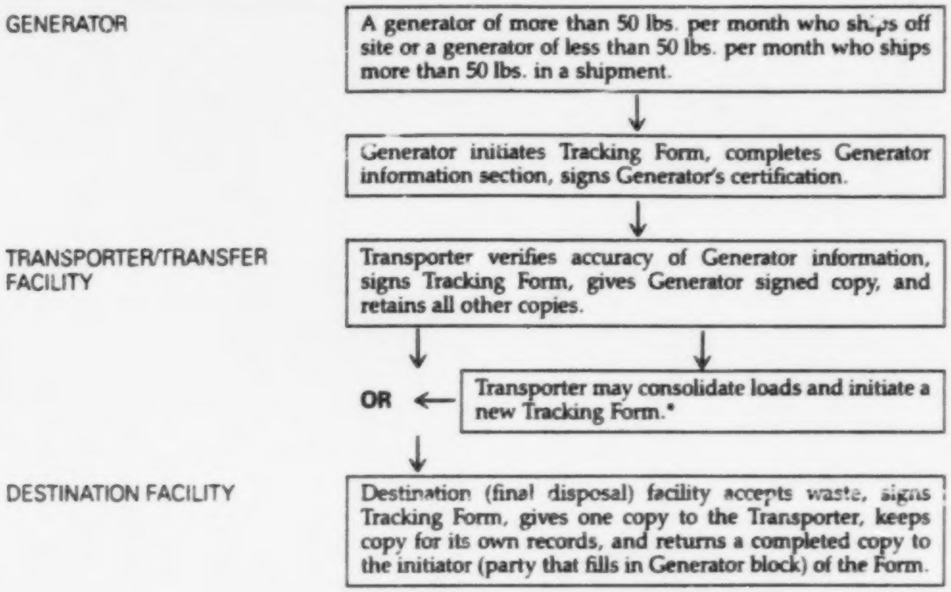
☐ Received in accordance with items 11, 12, & 13

Printed/Typed Name   Signature   Date

(If other than destination facility, indicate address, phone, and permit or ID no. in box 14.)

23. Discrepancy Box (Any discrepancies should be noted by item number and initials)

FIGURE 1. Medical waste tracking form.



A generator of more than 50 lbs. per month who ships off site or a generator of less than 50 lbs. per month who ships more than 50 lbs. in a shipment.

Generator initiates Tracking Form, completes Generator information section, signs Generator's certification.

Transporter verifies accuracy of Generator information, signs Tracking Form, gives Generator signed copy, and retains all other copies.

Transporter may consolidate loads and initiate a new Tracking Form.*

Destination (final disposal) facility accepts waste, signs Tracking Form, gives one copy to the Transporter, keeps copy for its own records, and returns a completed copy to the initiator (party that fills in Generator block) of the Form.

*Initiators of Tracking Forms become generators in effect under this Tracking System.

FIGURE 2. Medical waste tracking system. All medical waste shipments that must be accompanied by a tracking form are tracked from generator to final disposal, or destination facility.

The Waste Management System

Because it is helpful for those involved in the demonstration program to understand the roles of generators, transporters, and facilities, their roles are described here.

Generators

A person or institution located in a participating state, generating 50 pounds or more of regulated medical waste monthly and shipping it off site, is fully covered by the demonstration program. These generators must separate, package, label, mark, and track medical wastes according to the regulation.

Generators producing and shipping less than 50 pounds a month must also prepare their wastes properly for shipment. They may use a log to account for wastes, however, instead of a tracking form.

On the other hand, generators that dispose of waste on site or in the sewer system are not covered by the requirements of this program. Generators that treat and destroy waste on site, such as by incineration, are subject to certain reporting and recordkeeping requirements. Wastes that are treated and destroyed or disposed of on site or in sewers are not counted as part of the limit of 50 pounds per month. All medical wastes—even those treated, destroyed, and disposed on site—must be stored properly.

Transporters

Transporters must notify EPA of their intention to comply with the program to be allowed to accept regulated medical wastes for transport. EPA maintains a list of transporters who have notified EPA of their intent to transport regulated medical wastes generated in each participating state. This list is available to generators. Transporters must follow rules governing their vehicles and addressing tracking, recordkeeping, and reporting of waste shipments. They must also make sure that wastes they pick up have been properly prepared for shipping and that the tracking form is accurate.

Treatment, Destruction, and Disposal Facilities

The demonstration tracking program rules apply to owners and operators of treatment, destruction, and disposal facilities receiving regulated medical wastes. These facilities include incinerators, landfills, and treatment operations that grind, steam sterilize, or treat the waste with disinfectants, heat, or radiation.

Like generators and transporters, treatment, destruction, and disposal facilities must keep track of medical wastes and maintain records. Facilities must send a signed copy of the tracking form back to the generator or initiator of the tracking form when the wastes have been accepted for disposal. The facility owners or operators must investigate any discrepancies between the accompanying papers and the shipments they receive; if, after investigation, there is still a discrepancy, they must report it to EPA and the generator state agency.

Generator packaging medical waste

Transporter vehicle

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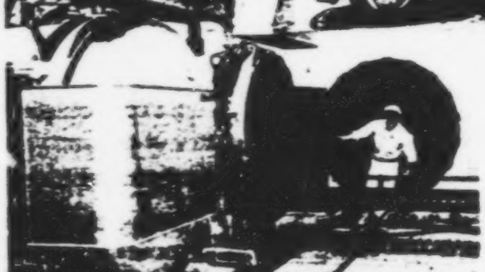


**Steam sterilizing,
or autoclaving,
before disposal**

Section 2:

A Detailed Guide for Generators of Regulated Medical Wastes

This section includes instructions for generators of regulated medical wastes to help them comply with the federal regulations. It outlines requirements for generators of more and less than 50 pounds a month. Checklists are included.

Profile of a Generator

Health care providers, veterinarians, research laboratories, and establishments involved in treating, diagnosing, or immunizing humans or animals probably generate medical wastes. (Table 1 presents some examples of regulated medical wastes that might be generated.) If so, they have to determine how they are affected by the medical waste demonstration tracking program. To understand their responsibilities, these generators must determine which of their wastes are regulated. They must then keep track of the quantity of regulated medical waste they generate and of how they dispose of it. All generators are affected by the program, but some may be subject only to certain parts (see Table 2).

A hospital is considered a single generator even though there might be many practitioners on staff, each producing medical waste. In contrast, a medical building shared by several practitioners, each with independent practices, is not a single generator; each practitioner is a generator.

TABLE 1. Examples of medical wastes generated by institutions or practitioners

Institution/Practitioner	Medical Wastes
Family physician	Syringes; tissue removed during minor surgery.
Dentist	Disposable needles; teeth and tissue. (Teeth given back to children are not considered waste in this program.)
Veterinarian	Syringes used for vaccination.
Hospital	Blood-soaked materials from the emergency room; needles, syringes, scalpels; amputated limbs and other body parts from surgery; and IV bags from patient-care rooms.
Laboratory	Blood vials; glassware that was in contact with infectious agents; discarded body fluids or specimens.

Generator marking box

Generators Subject to All Requirements

The following generators must comply with all program requirements.

Persons, institutions, or companies that

- are located in a participating state.
- generate 50 pounds or more of regulated medical waste monthly on site (on a contiguous piece of property).
- ship that waste off site for treatment, destruction, or disposal.

Vessels at port in a participating state where regulated medical wastes are taken to shore for transport and disposal. These vessels operate as co-generators with their shore bases, thus sharing responsibilities under the program.

Generators subject to the full requirements must

- follow all pre-transporting requirements: segregate, package, label, and mark.
- initiate a tracking form to track their wastes.
- use a transporter that has notified EPA of its intent to participate.
- comply with recordkeeping and reporting requirements.

TABLE 2. Medical waste generator requirements

Generator of	Pre-Transportation Requirements	Tracking and Reporting	Transporting	Recordkeeping
> 50 lb./month shipping waste off site	Must follow requirements.	Must use Tracking Form[1] and file Exception Reports, if necessary.	Must use transporter that has notified EPA of intent to participate.[1]	Must comply with recordkeeping and reporting requirements.
< 50 lb./month shipping > 50 lb./month off site in a shipment	Must follow requirements.	Must use Tracking Form[1] and file Exception Reports, if necessary.	Must use transporter that has notified EPA of intent to participate.[1]	Must comply with recordkeeping and reporting requirements.
< 50 lb./month shipping < 50 lb./month off site[3]	Must follow requirements.	May maintain a Log instead of using a Tracking Form; not required to file Exception Reports.	Must use transporter that has notified EPA of intent to participate or use own vehicle[2] or mail (sharps) by U.S. Postal Service.	Must comply with recordkeeping and reporting requirements.

[1] Except when shipping within institutions or company.
[2] Only when taking wastes to generator's place of business, or to a hospital or other facility with which there is a contract.
[3] See Table 3.

Generators with Special Requirements and Exemptions

Generators must determine the quantity of regulated medical waste they generate and ship off site in a month to see if they qualify for the special requirements or exemptions for small generators. Wastes disposed of on site or in sewers are not counted or tracked. Wastes that have been both treated and destroyed on site, such as incinerator ash, are not tracked either. Table 3 outlines generator exemptions and special requirements.

Pre-transporting Procedures

All regulated medical wastes that are to be transported to an off-site facility for treatment or disposal must be segregated and separated, packaged, labeled, and marked.

Segregating and Separating Wastes

Before packaging, medical waste generators must segregate the waste from general trash. If general trash is placed in a container with regulated medical waste, the trash must be handled as a regulated medical waste. Once segregated from general trash, medical waste must be separated to the extent practical into the following groups:

- sharps, such as needles, scalpels, glassware, and syringes, with residual fluids.
- fluids in quantities greater than 20 cubic centimeters.
- other regulated medical wastes such as body parts, blood-soaked bandages, and research animal carcasses.

TABLE 3. Generator exemptions and special requirements

Generator	PRE-TRANSPORTING				Tracking	Transporting	Disposing	Recordkeeping
	Packaging	Labeling	Marking	Storing				
< 50 lb./month shipping < 50 lb./month off site[1]	Must follow rules.	Must follow rules.	Must follow rules.	Must follow rules.	Exempt from using Tracking Form; must maintain a log.[2]	Must use transporter on EPA list or own (or authorized employee's) vehicle or send sharps by U.S. Mail.	If using own vehicle, must take wastes to own place(s) of business, a hospital, or a treatment destruction, or disposal facility with which there is an agreement.	Must maintain log for three years.
Institutional, with satellites or branches[3]	Must follow rules.	Must follow rules.	Must follow rules.	Must follow rules.	Exempt from using Tracking Form; must maintain a log.[4]	Must use transporter on EPA list or use own (or authorized employee's) vehicle	Must transport waste from a satellite or branch operation—original operation point—to central collection point within the same state.	Must maintain log for three years.
< 50 lb./month sending < 50 lb. of sharps/month by U.S. Mail	Must follow rules.	Must follow rules.	Must follow rules.	Must follow rules.	Exempt from using Tracking Form; send by registered mail, return receipt requested, showing delivery date and receiver's name and address; keep log.[5]	N/A	N/A	Must maintain receipt and log for three years.
Treating and destroying or disposing of wastes on site	Exempt	Exempt	Exempt	Must follow rules.	Must maintain log if waste treated and destroyed on site by method other than incineration.[6]	N/A	N/A	Must maintain log for three years.
Incinerating own waste on site	Exempt	Exempt	Exempt	Must follow rules.	Must comply with recordkeeping and reporting requirements (40 CFR Part 259, Subpart G).	N/A	N/A	N/A

---

[1] Figure 3 shows how a small generator might manage medical wastes.

[2] See Figure 4.

[3] Exemption ends when waste is shipped off site from central collection point.

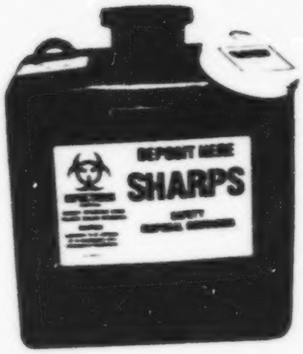
[4] See Figure 5.

[5] Log must show date, name and address of facility, weight, and category of waste.

[6] Log must show weight of all waste treated and approximate percentage that is medical.

Packaging Regulated Medical Wastes

All regulated medical wastes must be placed in a container or combination of containers that are rigid and leak resistant, impervious to moisture, strong enough to prevent tearing or bursting under normal handling, and sealed securely. Often generators place medical waste other than sharps or fluids into plastic bags; the transporter then puts the bags into a box.



Sharps and fluids may also be boxed by the transporter. But first sharps, such as needles and scalpels, must be packaged in a rigid container resistant to punctures; fluids must be poured into a container resistant to breaking and equipped with a tightly fitting stopper or lid.

Oversized medical waste—animal carcasses and other items too large for standard bags and containers—should be handled and transported, minimizing contact with transportation workers, other handlers, and the public.

Non-rigid packaging and inner liners, such as plastic bags, are likely to become contaminated through use. Therefore, they are considered regulated medical waste and may not be reused. Rigid containers, including bins, barrels, and boxes can be reused, but must be made free of any visible contamination. If rigid containers cannot be cleansed of visible contamination, then they too are handled as regulated medical wastes.

Example 1

Doctors in a small group medical practice accumulate used needles and syringes, cultures of infectious agents, and other regulated medical wastes resulting from tests or out-patient surgery. They plan to dispose of the wastes off site. Because the doctors are in a group practice, the waste from each is added together. They must make sure that the wastes are segregated from other trash and are packaged and labeled properly at the office where they first became medical wastes. The wastes from their combined practice amount to less than 50 pounds a month. One of the doctors carries it in his own private car to a hospital where it is incinerated. The small group practice must have a written agreement that the facility will accept the waste, and they must maintain a log for three years. The log contains the weight and category of the medical waste, its date of shipment, the name and address of the facility receiving the waste, and the signature of the doctor who transported the waste to the facility.

Example 2

The same group medical practice arranges to have the waste picked up by a transporter on the EPA notification list. In this case, the doctors are responsible for preparing the waste for shipping and keeping the doctors' office log. One of the doctors can assume the paperwork duties and make all the arrangements, but the group of doctors remains responsible for all the wastes.

Example 3

Several doctors have unrelated practices in a single medical building. Each practice produces less than 50 pounds of medical waste in a month. The doctors choose to arrange for a single transporter. In this case, each doctor keeps a separate log and packages, labels, and marks his or her waste properly.

FIGURE 3. Examples for small generators: physicians, veterinarians, dentists, and other health services.

GENERATOR SHIPMENT LOG

Transporter Name and Address	Transporter State Permit or ID Number	Quantity and Category of Waste Transported		Date of Shipment	Signature of Representative Accepting Waste for Transport
		Containers	Pounds		
		Untreated		__/__/__	
		Treated			
		Untreated		__/__/__	
		Treated			
		Untreated		__/__/__	
		Treated			
		Untreated		__/__/__	
		Treated			
		Untreated		__/__/__	
		Treated			
		Untreated		__/__/__	
		Treated			
		Untreated		__/__/__	
		Treated			

FIGURE 4. Generator shipment log for generators of less than 50 pounds of regulated medical waste per month, who ship less than 50 pounds per shipment.

OPERATING LOG—ORIGINAL GENERATION POINT

- Date of shipment.
- Weight of waste transported, by category: treated or untreated.
- Address/location of central collection point.
- Signature of the generator's employee who accepts and transports the waste

OPERATING LOG—CENTRAL COLLECTION POINT

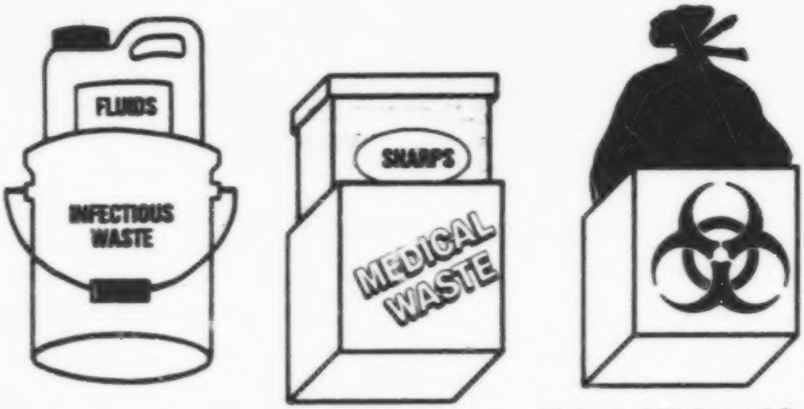
- Date of receipt.
- Quantity by weight and waste category (treated or untreated) accepted, by category.
- Address/location of original generation point.
- Signature of operator who accepts the waste.

The logs are retained for three years.

FIGURE 5. Log for institutions transporting between their own facilities.

Labeling

Generators shipping untreated medical wastes are required to label packaging, or containers, to alert handlers. Generators must affix a water-resistant label to all packaging of untreated wastes. When there is inner and outer packaging, or containers, each container of waste must be labeled INFECTIOUS WASTE or MEDICAL WASTE or display the universal biohazard symbol as illustrated below. Red plastic bags, when used as inner packaging for untreated wastes, need no labels. However, the outer packaging must still carry the proper label or symbol.

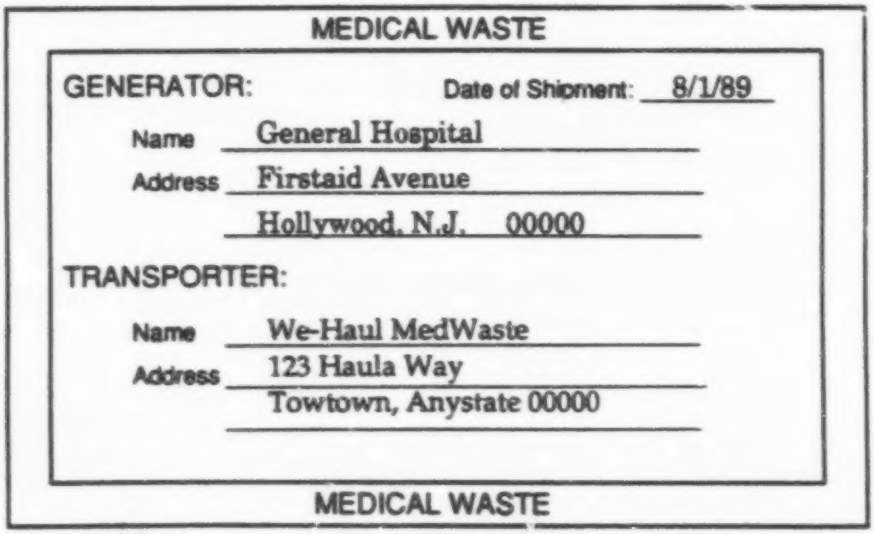


Universal Biohazard Symbol

Treated medical wastes do not require such warning labels, but must be marked as specified below.

Marking

Before shipment, all packaging—inner and outer—must be marked with indelible ink or with a water-resistant identification tag. Each inner container, if used, must show the name and identifying numbers or address of the generator. Each outer container must identify the contents as medical waste and include the information as it appears on the sample tag shown below.



MEDICAL WASTE

GENERATOR: Date of Shipment: 8/1/89

Name General Hospital

Address Firstaid Avenue

Hollywood, N.J. 00000

TRANSPORTER:

Name We-Haul MedWaste

Address 123 Haula Way

Towtown, Anystate 00000

MEDICAL WASTE

Storing Medical Wastes

Some facilities store their medical wastes before disposing of them on site or sending them to another location for disposal. Stored medical waste must be

- protected from water, rain, and wind.
- kept nonputrescent.
- kept in locked dumpsters, sheds, tractor trailers, or other secure containers, if outdoors.
- protected from unauthorized employees and animals and pests.

Tracking Medical Wastes

The full tracking system (see Figure 6), including tracking forms, must be used if

- generators of 50 pounds or more a month, including vessels, transport regulated medical waste off site.
- generators of less than 50 pounds a month ship 50 pounds or more in a single shipment.

For generators that initiate tracking forms, a tracking form may be obtained from different sources, depending on the waste destination. If the waste is shipped to a participating state, which prints the form, the transporter must provide that state's form to the generator. If the waste is shipped to a nonparticipating state or a state that does not print the form, the generator must get the form from its own state. But if the generator state does not require its own form, the generator may reproduce the tracking form in this booklet or obtain a copy of the federal form from another source, such as the transporter.

Preparing a Tracking Form

The generator must prepare enough copies of the tracking form for itself, transporters as required, all intermediate handlers, the owner or operator of the final facility accepting the waste, and one copy to be returned to the generator. Each handler keeps a copy for its own records. When the final disposal site or destination facility accepts the waste, a copy is returned to the generator with all signatures in place.

The tracking form is usually a four-part form: Copy 1 travels with the waste and is returned to the generator by the destination facility; copy 2 is retained by the destination facility; copy 3 is retained by the transporter; and copy 4 is held by the generator when the waste is released for transport. If more than one transporter is used or an intermediate handler is required, then enough copies of the form are needed for each to keep a copy. More specific instructions appear in 40 CFR Part 259, Appendix I. If shipping by rail directly from the site, a generator should refer to 40 CFR 259.52(e) for specific instructions.

Exception Reporting

Within 35 days, the generator should receive a copy of the completed tracking form bearing the signature of the destination facility's owner or operator. If a form is not received, a generator must try to determine the location of the waste.

If, after 45 days, a signed tracking form is still not received, then an Exception Report must be filed by the next day with the state and the EPA Regional Administrator. The Exception Report includes both a letter from the generator explaining its efforts to locate the waste and the results of such efforts, and a legible copy of the original tracking form.

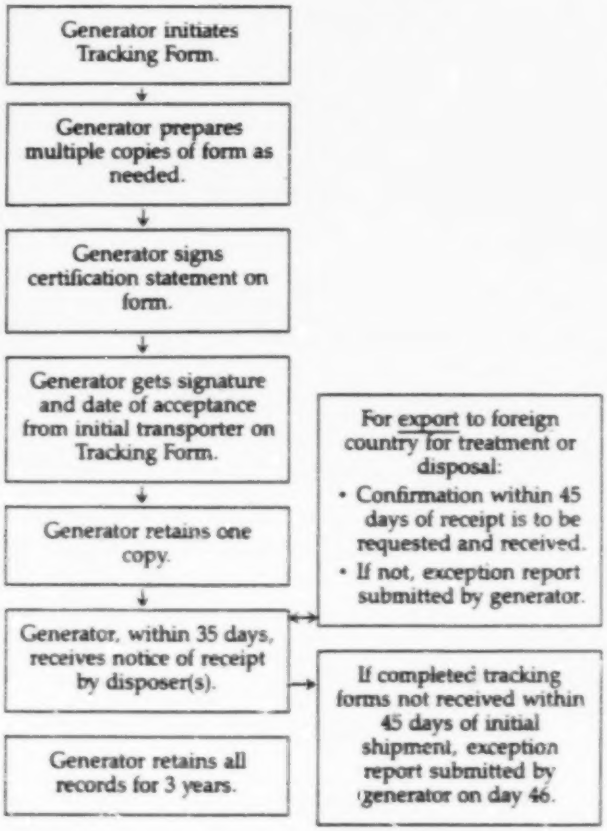

Generator initiates Tracking Form.
Generator prepares multiple copies of form as needed.
Generator signs certification statement on form.
Generator gets signature and date of acceptance from initial transporter on Tracking Form.
Generator retains one copy.
Generator, within 35 days, receives notice of receipt by disposer(s).
Generator retains all records for 3 years.
For export to foreign country for treatment or disposal:
• Confirmation within 45 days of receipt is to be requested and received.
• If not, exception report submitted by generator.
If completed tracking forms not received within 45 days of initial shipment, exception report submitted by generator on day 46.

FIGURE 6. Tracking medical wastes.

Exporting Medical Wastes

Generators exporting regulated medical waste to another country for treatment, destruction, or disposal must request written confirmation from the destination facility that the waste was received. If notification has not been received within 45 days, the generator has to submit an Exception Report by the 46th day.

Keeping Records

As part of routine recordkeeping, generators using the tracking system are to maintain information for three years about medical waste transporters with whom they contract. These records must include copies of all tracking forms. All logs, receipts, and Exception Reports must also be retained for three years. EPA or state agencies may ask to inspect these records or ask the generators to provide copies.

Other Reports

EPA may require generators to provide additional reports concerning quantities of regulated medical waste and their management methods. Furthermore, EPA may require an inspection of a generator's premises.

Medical Waste Generator Checklists

Do These Rules Apply To You?

A "person" under these rules is an individual, trust, firm, joint stock company, corporation (including a government corporation), partnership, association, state, municipality, commission, political subdivision of a state, any interstate body, or any department, agency or instrumentality of the United States.

________ Person generates regulated medical waste in a participating state. (If yes, continue.)

________ Port receiving regulated medical waste from a vessel is located in a participating state. (If yes, continue.)

________ Vessel from which regulated medical waste is carried to shore in a participating state. (If yes, continue.)

________ Person generates on site 50 pounds a month or more of regulated medical waste and sends it off site. (If yes, continue to Full Requirements Checklist.)

________ Person generates less than 50 pounds a month, but ships more than 50 pounds in a shipment. (If yes, continue to Full Requirements Checklist.)

________ Person incinerates medical waste on site. (If yes, see 40 CFR Part 259, Subpart G.)

________ Person generates regulated medical waste and treats and destroys it on site. (If yes, exempt from this program for that waste, except for maintaining a log. May be subject to state regulations.)

________ Person transports within its own facility's branch or satellite operations—from generation point to central collection point. (If yes, exempt from tracking requirements and certain transporting requirements. See Figure 5 Log.)

________ Person generates less than 50 pounds a month and sends off site less than 50 pounds in a shipment. (If yes, see Figures 3 and 4, and Small Generator Checklist.)

________ Person generates less than 50 pounds a month and uses U.S. Postal Service to transport sharps. (If yes, see specific requirements and Small Generator Checklist.)

Full Requirements Checklist

Shipments of More than 50 Pounds

If you are subject to the full requirements, the following list is designed to help you comply.

- ________ Do you separate regulated medical waste from general trash?
- ________ Do you separate sharps and fluids from each other and from other regulated medical wastes?
- ________ Are sharps in puncture-resistant containers and are fluids in break-resistant, tightly-lidded or stoppered containers?
- ________ Are all IV bags and sharps, such as needles and syringes, from patient-care rooms included as regulated medical waste?
- ________ Are the packages rigid, resistant to leaks, impervious to moisture, strong enough to prevent tearing or bursting, and sealed?
- ________ Are they properly labeled and marked?
- ________ Do you store these wastes properly while awaiting shipment?
- ________ Do you contract with a transporter on the EPA notification list?
- ________ Do you have enough copies of the tracking form so that each transporter, intermediate handler, and the destination facility may retain a copy, with one left over to be sent back to you for your recordkeeping requirements?
- ________ Do you fill out the form accurately and sign the certification box? (See 40 CFR Part 259, Appendix I: Medical Waste Tracking Form and Instructions.)
- ________ Do you get a signature from the first transporter along with your copy of the signed form?

Do you understand that

- ________ Your copy of each tracking form is to be retained for three years?
- ________ When the waste is accepted at a destination facility a copy of the completed, signed tracking form should be received within 35 days and, if it has not:
  - ________ It is your responsibility to find out what happened to the waste; and
  - ________ You must file an Exception Report if a completed tracking form is not received within 45 days?
- ________ You must allow EPA inspection, if requested?
- ________ You must also follow all applicable state and local regulations?

Small Generators Checklist

Generators of Less Than 50 Pounds Per Month Who Ship Less Than 50 Pounds Per Shipment

If you are a small generator, the following list is designed to help you comply with the requirements.

________ Do you keep regulated medical wastes separate from general trash?

________ Do you separate sharps and fluids from each other and other regulated medical wastes?

________ Are sharps in puncture-resistant containers and are fluids in break-resistant, tightly-lidded or stoppered containers?

________ Are the packages rigid, resistant to leaks, impervious to moisture, strong enough to prevent tearing or bursting, and sealed?

________ Are they properly labeled and marked?

________ Do you store these wastes properly while awaiting shipment?

________ Do you contract with a transporter on the EPA notification list;

OR

________ Do you personally take the waste in your own vehicles to a hospital or other facility that has agreed to accept it?

________ If so, do you record the shipment in a log (see Figure 4)?

OR

________ Do you mail sharps using the U.S. Postal Service, keeping receipts and an operating log?

________ Do you understand that you must retain records for three years?

________ Do you understand that you must also follow applicable state and local rules?

Glossary

Following are the classes of regulated medical wastes and a description of each.

Cultures and Stocks	Cultures and stocks of infectious agents and associated biologicals including: cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.
Pathological Wastes	Human pathological wastes, including tissues, organs, and body parts and body fluids that are removed during surgery or autopsy or other medical procedures, and specimens of body fluids and their containers.
Human Blood and Blood Products	Liquid waste human blood; products of blood; items saturated and/or dripping with human blood; or items that were saturated and/or dripping with human blood that are now caked with dried human blood including serum, plasma, and other blood components, and their containers, which were used or intended for use in either patient care, testing and laboratory analysis, or the development of pharmaceuticals. Intravenous bags are also included in this category.
Sharps	Sharps that have been used in animal or human patient care or treatment or in medical, research, or industrial laboratories. These include hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.
Animal Waste	Contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals, or testing of pharmaceuticals.
Isolation Wastes	Biological waste and discarded materials contaminated with blood, excretion, exudates, or secretions from humans who are isolated to protect others from certain highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.
Unused Sharps	The following unused, discarded sharps: hypodermic needles, suture needles, syringes, and scalpel blades.

The following terms are defined here to address the management of medical wastes. They may be different from those federal definitions used for solid or hazardous waste.

Biologicals	Preparations made from living organisms and their products, including vaccines, cultures, etc. intended for use in diagnosing, immunizing, or treating humans or animals, or in related research.
Blood Products	Any product derived from human blood, including but not limited to blood plasma, platelets, red or white blood corpuscles, and other derived licensed products, such as interferon.
Body Fluids	Liquid emanating or derived from humans and limited to blood; cerebrospinal, synovial, pleural, peritoneal, and pericardial fluids; and semen and vaginal secretions.
Central Collection Point	A location where a generator consolidates regulated medical waste brought together from original generation points prior to its transport off-site or its treatment on-site.
Container	Any portable device in which a material is stored, transported, disposed of, or otherwise handled. The term container, when describing the packaging requirements, does not include items that are regulated medical waste.
Decontamination	The process of reducing or eliminating the presence of harmful substances, such as infectious agents, so as to reduce the likelihood of disease transmission from those substances.
Destination Facility	The disposal facility, the incineration facility, or the facility that both treats and destroys regulated medical waste to which medical wastes are shipped.
Destroyed Regulated Medical Waste	Regulated medical waste that has been ruined, torn apart, or mutilated through processes such as thermal treatment, melting, shredding, grinding, tearing, or breaking, so that it is no longer generally recognizable as medical waste, but has not yet been treated. It does not mean compacted regulated medical waste.

Destruction Facility	A facility that destroys regulated medical waste by ruining or mutilating it, or tearing it apart.
Facility	All contiguous land and structures, other appurtenances, and improvements on the land used for treating, destroying, storing, or disposing of regulated medical waste. A facility may consist of several treatment, destruction, storage, or disposal operational units.
Generator	Any person, by site, whose act or process produces regulated medical waste or whose act first causes a regulated medical waste to become subject to regulation. In the case where more than one person (e.g., doctors with separate medical practices) is located in the same building, each individual business entity is a separate generator. [Note: see definition of "person."]
Infectious Agent	Any organism (such as a virus or a bacteria) that is capable of being communicated by invasion and multiplication in body tissues and capable of causing disease or adverse health impacts in humans.
Intermediate Handler	A facility that either treats regulated medical waste or destroys regulated medical waste but does not do both. The term does not include transporters.
Laboratory	Any research, analytical, or clinical facility that performs health care-related analysis or service. This includes medical, pathological, pharmaceutical, and other research, commercial, or industrial laboratories.
Landfill	A disposal facility or part of a facility where regulated medical waste is placed in or on the land and which is not a land treatment facility, a surface impoundment, or an injection well.
Medical Waste	Any solid waste which is generated in the diagnosis, treatment (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. The term does not include any hazardous waste identified or listed under 40 CFR Part 261 or any household waste as defined in 40 CFR §261.4(b)(1).
On-site	The same or geographically contiguous property which may be divided by public or private right of way, provided the entrance and exit between the properties is at a crossroads intersection, and access is by crossing as opposed to going along the right of way. Non-contiguous properties owned by the same person but connected by a right of way which he controls and to which the public does not have access is also considered on-site property.
Original Generation Point	Location where regulated medical waste first becomes waste (is "generated").
Oversized Regulated Medical Waste	Medical waste that is too large to be placed in plastic bags or standard containers.
Package or Outside Package	The packaging/container and its contents.
Packaging	The assembly of one or more containers and any other components necessary to assure minimum compliance with the program's packaging requirements.
Person	An individual, trust, firm, joint stock company, corporation (including a government corporation), partnership, association, state, municipality, commission, political subdivision of a state, any interstate body, or any department, agency or instrumentality of the United States.
Storage	The temporary holding of regulated medical wastes at a designated accumulation area before treatment, disposal, or transport to another location.
Transfer Facility	Any transportation-related facility including loading docks, parking areas, storage areas and other similar areas where shipments of regulated medical waste are held during the course of transportation. Also, a location in which medical waste is transferred between two vehicles.
Treated Regulated Medical Waste	Regulated medical waste that has been treated to substantially reduce or eliminate its potential for causing disease, but that has not yet been destroyed.
Treatment	When used to refer to waste handling, it means any method, technique, or process designed to change the biological character or composition of any regulated medical waste so as to substantially reduce or eliminate its potential for causing disease.

Appendix

Participating State Programs

Connecticut Department of
Environmental Protection
Solid Waste Management Unit
State Office Building
165 Capitol Avenue
Hartford, CT 06106
(203) 566-5847
(Region I)

New Jersey Department of
Environmental Protection
Division of Solid Waste Management
401 East State Street, CN 414
Trenton, NJ 08625
(609) 984-7840
(Region II)

New York State Department of
Environmental Conservation
50 Wolf Road
Albany, NY 12233
Tracking form: (518) 485-8394
Other inquiries: (518) 457-3254
(Region II)

Rhode Island Department of
Environmental Management
9 Hayes Street
Providence, RI 02907-5003
(401) 277-2771
(Region I)

Puerto Rico Environmental
Quality Board
Box 11488
Santurce, PR 00910
(809) 722-0439
(Region II)

EPA Regional Offices

Region I
State Waste Programs
Branch
JFK Federal Building
Boston, MA 02203
(617) 573-5758

Region II
Air and Waste
Management Division
26 Federal Plaza
New York, NY 10278
(212) 264-5166

Caribbean Field Office
(809) 729-6920

Region III
Waste Management
Branch
841 Chestnut Building
Philadelphia, PA 19107
(215) 597-2842

Region IV
Hazardous Waste
Management Division
345 Courtland Street, N.E.
Atlanta, GA 30365
(404) 347-3016

Region V
RCRA Activities
230 S. Dearborn Street
Chicago, IL 60604
(312) 353-9510

Region VI
Air and Hazardous Materials
Division
1445 Ross Avenue
Suite 1200
Dallas, TX 75270
(214) 655-6652

Region VII
RCRA Branch
726 Minnesota Avenue
Kansas City, KS 66101
(913) 236-2856

Region VIII
Waste Management Division
999 18th Street, Suite 500
Denver, CO 80202
(303) 293-1496

Region IX
Toxics and Waste
Management
215 Fremont Street
San Francisco, CA 94105
(415) 974-8388

Region X
Waste Management Branch
1200 Sixth Avenue
Seattle, WA 98101
(206) 442-6501

United States
Environmental Protection
Agency

Solid Waste and
Emergency Response
(OS-305)
Washington, DC 20460

EPA/530-SW-89-022
September 1989

EPA

Managing and Tracking Medical Wastes

A Guide to the Federal Program for Transporters

Printed on recycled paper

Introduction

In response to the growing public concern over mismanagement of medical wastes, Congress enacted the *Medical Waste Tracking Act*. The Act charges the Environmental Protection Agency with responsibility for implementing a two-year demonstration medical waste tracking program that will help determine the best medical waste management procedures for the future. The program's goal is to find an effective means to ensure that regulated medical wastes get from their point of generation to their point of disposal.

Generators of regulated medical wastes will be part of the new demonstration tracking program in the States of Connecticut, New Jersey, New York, and Rhode Island, and the Commonwealth of Puerto Rico. Transporters and facilities that store, treat, destroy, and dispose of these wastes will also be part of the program.

This guide offers general information about the tracking program (Section 1) and specific instructions for transporters of regulated medical waste (Section 2). Section 2 includes requirements for transporters, including owners and operators of transfer facilities that carry regulated medical waste generated in a participating state. It also includes requirements for the vehicles used by transporters. Separate guides in this series are provided for generators and facilities that treat, destroy, and dispose of regulated medical wastes.

This guide describes the federal program only. It is designed to help transporters comply with the program. For more complete information, transporters should refer to "Standards for the Tracking and Management of Medical Waste," interim final rule (40 CFR Part 259). In addition, states participating in the program have their own rules for managing medical waste. For further assistance, addresses and phone numbers of EPA Regional Offices and participating state programs are listed in Appendix A.

For additional copies of *Managing and Tracking Medical Wastes* or a copy of 40 CFR Part 259, call the RCRA Hotline at (800) 424-9346 or, in Washington, D.C., 382-3000.

The cooperation of all participants in the management of regulated medical waste will assure the success of this important demonstration program and reduce public exposure to the waste.

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Section 1:

The Medical Waste Tracking Program

In response to public concern over the mismanagement of medical wastes, the *Medical Waste Tracking Act* was enacted in the fall of 1988. The law directs the Environmental Protection Agency (EPA) to establish a two-year demonstration program for tracking medical wastes.

Under this law, EPA has issued regulations entitled "Standards for the Tracking and Management of Medical Waste" (40 CFR Part 259). The regulations list the medical wastes to be tracked and cover standards for separating, packaging, and labeling medical wastes before sending them for treatment or disposal. The results of the demonstration program are intended to help determine whether such a program should be extended nationwide.

> The *Medical Waste Tracking Act* amends the *Resource Conservation and Recovery Act* (RCRA) by adding Subtitle J. It defines medical waste as " . . . any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. . . . "

Participating in the demonstration program are the States of Connecticut, New Jersey, New York, and Rhode Island, and the Commonwealth of Puerto Rico. The regulation is an interim final rule. It will be in effect for two years, until June 22, 1991. In Connecticut, New Jersey, and New York, the program is effective beginning June 22, 1989; in Rhode Island and Puerto Rico, the program is effective beginning July 24, 1989.

The demonstration program involves **only** regulated medical wastes **generated in one of the states** participating in the program, even when these wastes leave the state. The program sets up a system for tracking the waste from the generator to the disposal site. A tracking form that accompanies this waste is signed and a copy is retained by a representative of the waste generator and each transporter, transfer station, and treatment, destruction, and disposal facility handling it. When the final disposer—the destination facility—accepts the waste, a copy of the signed tracking form is returned to the generator. In this way, the generator is assured that the waste was received for disposal. The tracking system includes "exception" and "discrepancy" reporting to alert EPA and the states if wastes are not being handled properly.

To minimize contact with regulated medical wastes by workers, handlers, and the public, the program includes specific requirements for segregating, packaging, labeling, marking, and storing medical wastes before they are shipped to another site for treatment, destruction, or disposal. Other requirements include recordkeeping, reporting, and enforcement. EPA will evaluate the success of the program and report the results to Congress.

Waste Managers Participation

This booklet is intended to help transporters of regulated medical wastes generated in the participating states comply with the federal rules. Transporters must also follow rules required by the individual states and should check with state officials for clarification of state rules. While participating states use the same basic tracking form as EPA's, some states might regulate more wastes or require special permits or licenses. Participating states are authorized to enforce this program.

The demonstration program includes medical waste generators in participating states; transporters of those wastes; and owners and operators of treatment, destruction, and disposal facilities that manage waste generated in participating states, even if their facilities are located in nonparticipating states. Similarly, the program includes transporters carrying regulated medical wastes from participating states, even if the wastes are then taken to nonparticipating states. The program includes vessels and transporters that take medical wastes to shore from ships docked in participating states. Federal facilities generating regulated medical wastes in participating states are also covered under this program.

Regulated Medical Wastes

Medical wastes affected by the pilot program include

- cultures and stocks of infectious agents.
- human blood and blood products.
- human pathological wastes, including those from surgery and autopsy.
- contaminated animal carcasses from medical research.
- wastes from patients isolated with highly communicable diseases.
- all used sharp implements, such as needles and scalpels, and certain unused sharps.

These regulated medical wastes fall into two categories: untreated or treated. The Glossary provides detailed descriptions of these medical wastes.

The demonstration program focuses on wastes that have been improperly managed and are most likely to pose a substantial threat to human health and the environment. However, any additional waste that a health care professional believes may pose a risk should be handled as a regulated medical waste.

Mixtures of regulated medical waste and general trash are regulated as medical waste. Mixtures of regulated medical waste and hazardous waste are usually regulated as hazardous waste. However, if medical waste is mixed with hazardous waste, which falls under the small quantity hazardous waste exemption, then the waste mixture must be tracked as medical waste under this program.

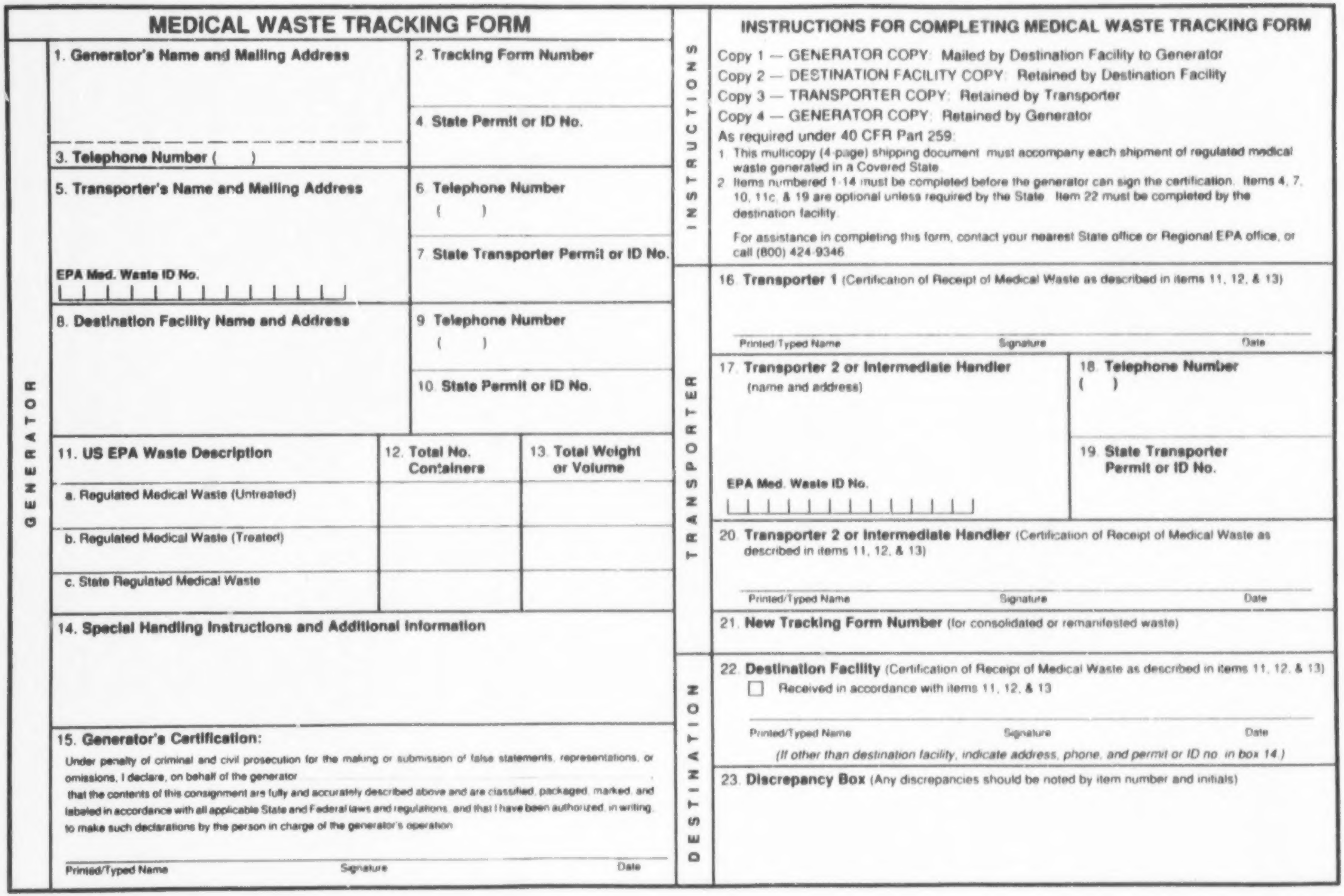
Pre-Transporting Procedures

Regulated medical wastes that are to be transported to an off-site facility for treatment or disposal must be properly prepared for shipping. First, the wastes must be separated from general trash, and then sharp items, fluids, and other medical wastes must be separated from each other to the extent possible. They are then packaged to prevent tearing, breaking, or leaking during shipping and handling. (See Appendix B for packaging, labeling, and marking requirements.)

Packages are to be labeled and marked to identify the contents of the package and the generator and transporter of the waste. In addition, stored wastes must be maintained to prevent them from coming into contact with workers or the public.

Tracking Regulated Medical Wastes

At the core of the medical waste demonstration tracking system is a MEDICAL WASTE TRACKING FORM (see Figure 1). This form must accompany each off-site shipment that weighs 50 pounds or more. Shipments from generators of less than 50 pounds a month may be combined onto one tracking form by the transporter. Generators, transporters, and treatment, destruction, and disposal facilities are responsible for filling in, forwarding, and retaining a copy of this form for their records. Figure 2 illustrates how the medical waste tracking system works.



MEDICAL WASTE TRACKING FORM

GENERATOR

1. Generator's Name and Mailing Address

2. Tracking Form Number

3. Telephone Number (   )

4. State Permit or ID No.

5. Transporter's Name and Mailing Address

EPA Med. Waste ID No.

6. Telephone Number
(   )

7. State Transporter Permit or ID No.

8. Destination Facility Name and Address

9. Telephone Number
(   )

10. State Permit or ID No.

11. US EPA Waste Description	**12. Total No. Containers**	**13. Total Weight or Volume**
a. Regulated Medical Waste (Untreated)		
b. Regulated Medical Waste (Treated)		
c. State Regulated Medical Waste		

14. Special Handling Instructions and Additional Information

15. Generator's Certification:

Under penalty of criminal and civil prosecution for the making or submission of false statements, representations, or omissions, I declare, on behalf of the generator ______ that the contents of this consignment are fully and accurately described above and are classified, packaged, marked, and labeled in accordance with all applicable State and Federal laws and regulations, and that I have been authorized, in writing, to make such declarations by the person in charge of the generator's operation.

Printed/Typed Name   Signature   Date

INSTRUCTIONS

INSTRUCTIONS FOR COMPLETING MEDICAL WASTE TRACKING FORM

Copy 1 — GENERATOR COPY: Mailed by Destination Facility to Generator
Copy 2 — DESTINATION FACILITY COPY: Retained by Destination Facility
Copy 3 — TRANSPORTER COPY: Retained by Transporter
Copy 4 — GENERATOR COPY: Retained by Generator

As required under 40 CFR Part 259:

1. This multicopy (4-page) shipping document must accompany each shipment of regulated medical waste generated in a Covered State.
2. Items numbered 1-14 must be completed before the generator can sign the certification. Items 4, 7, 10, 11c, & 19 are optional unless required by the State. Item 22 must be completed by the destination facility.

For assistance in completing this form, contact your nearest State office or Regional EPA office, or call (800) 424-9346

TRANSPORTER

16. Transporter 1 (Certification of Receipt of Medical Waste as described in items 11, 12, & 13)

Printed/Typed Name   Signature   Date

17. Transporter 2 or Intermediate Handler
(name and address)

EPA Med. Waste ID No.

18. Telephone Number
(   )

19. State Transporter Permit or ID No.

20. Transporter 2 or Intermediate Handler (Certification of Receipt of Medical Waste as described in items 11, 12, & 13)

Printed/Typed Name   Signature   Date

21. New Tracking Form Number (for consolidated or remanifested waste)

DESTINATION

22. Destination Facility (Certification of Receipt of Medical Waste as described in items 11, 12, & 13)

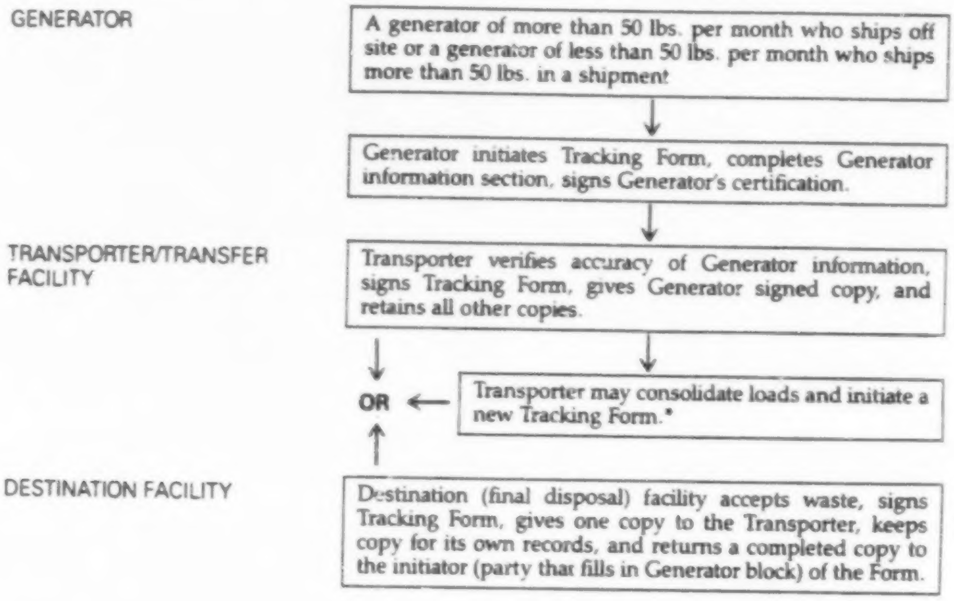
☐ Received in accordance with items 11, 12, & 13

Printed/Typed Name   Signature   Date

(If other than destination facility, indicate address, phone, and permit or ID no. in box 14.)

23. Discrepancy Box (Any discrepancies should be noted by item number and initials)

FIGURE 1. Medical waste tracking form.


GENERATOR
A generator of more than 50 lbs. per month who ships off site or a generator of less than 50 lbs. per month who ships more than 50 lbs. in a shipment
Generator initiates Tracking Form, completes Generator information section, signs Generator's certification.
TRANSPORTER/TRANSFER FACILITY
Transporter verifies accuracy of Generator information, signs Tracking Form, gives Generator signed copy, and retains all other copies.
OR
Transporter may consolidate loads and initiate a new Tracking Form.*
DESTINATION FACILITY
Destination (final disposal) facility accepts waste, signs Tracking Form, gives one copy to the Transporter, keeps copy for its own records, and returns a completed copy to the initiator (party that fills in Generator block) of the Form.

*Initiators of Tracking Forms become Generators in effect under this Tracking System.

FIGURE 2. All medical waste shipments required to be accompanied by a tracking form are tracked from generator to final disposal, or destination facility.

The Waste Management System

Because it is helpful for those involved in the demonstration program to understand the roles of generators, transporters, and facilities, their roles are presented here.

Generators

A person or institution located in a participating state, generating 50 pounds or more of regulated medical waste monthly and shipping it off site, is fully covered by the demonstration program. These generators must separate, package, label, mark, and track medical wastes according to the regulation. Generators often hire transporters to provide many of these services, including supplying them with appropriate tracking forms.

Generators producing and shipping less than 50 pounds a month must also prepare their wastes properly for shipment. They may use a log to account for wastes, however, instead of a tracking form.

On the other hand, generators that dispose of waste on site or in the sewer system are not covered by the requirements of this program. Generators that treat and destroy waste on site, such as by incineration, are subject to certain reporting and recordkeeping requirements. Wastes that are treated and destroyed or disposed of on site or in sewers are not counted as part of the 50 pound monthly limit. All medical wastes—even those treated, destroyed, and disposed on site—must be stored properly.

Transporters

Transporters must notify EPA of their intention to comply with the program to be allowed to accept regulated medical wastes for transport. EPA maintains a list of transporters who have notified EPA of their intent to transport regulated medical wastes generated in each participating state. This list is available to generators. Transporters must follow rules governing their vehicles and addressing tracking, recordkeeping, and reporting of waste shipments. They must also make sure that wastes they pick up have been properly prepared for shipping and that the tracking form is accurate.

Treatment, Destruction, and Disposal Facilities

The demonstration tracking program rules apply to owners and operators of treatment, destruction, and disposal facilities receiving regulated medical wastes. These facilities include incinerators, landfills, and treatment operations that grind, steam sterilize, or treat the waste with disinfectants, heat, or radiation.

Like generators and transporters, treatment, destruction, and disposal facilities must keep track of medical wastes and maintain records. Facilities must send a signed copy of the tracking form back to the generator or initiator of the tracking form when the wastes have been accepted for disposal. The facility owners or operators must investigate any discrepancies between the accompanying papers and the shipments they receive; if, after investigation, there is still a discrepancy, they must report it to EPA and the generator state agency.

Generator packaging medical waste

Transporter vehicle

Steam sterilizing, or autoclaving, before disposal

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Section 2: A Detailed Guide for Transporters of Regulated Medical Waste

This section presents instructions for transporters of regulated medical wastes to help them comply with the federal programs. Detailed checklists are included.

Profile of a Transporter

All transporters of regulated medical waste generated in participating states are covered by the medical waste demonstration program. Transfer facilities that handle regulated medical wastes, generators that transport their own wastes, and intermediate handlers that carry regulated medical wastes are also subject to the transporter requirements in this program.

Transporters must determine if they intend to handle regulated medical wastes originating in participating states. If so, they must notify EPA of their intention. Transporters need to know which of the medical wastes they transport are regulated and what special handling procedures apply. All transporters carrying regulated medical waste generated in participating states are affected by the program, even if they carry waste to a nonparticipating state.

Transporters Subject to All Requirements

In general, transporters of regulated medical waste must comply with all applicable requirements of the regulation. They must

- notify EPA of their intent to handle regulated medical waste originating in a participating state.
- agree to follow rules governing the vehicles they use.
- make sure that the wastes are properly packaged, labeled, and marked.
- comply with rules for tracking, recordkeeping, and reporting of waste shipments.

Transporters may also be

- required to initiate tracking forms.
- subject to state requirements for permitting, licensing, and registering.

Special Exceptions

Generators transporting their own medical wastes should refer to *Managing and Tracking Medical Wastes: A Guide to the Federal Program for Generators*. In addition, the following transporters are subject to exceptions to the regulations:

Transporters may arrange with generators of less than 50 pounds of regulated medical waste a month to accept individual shipments of less than 50 pounds without preparing a tracking form. In these instances, the transporter and the generator are required to maintain logs containing shipment information. The transporter must carry this log in the vehicle. Before transferring custody of these logged wastes, the transporter must initiate a tracking form, as a surrogate generator, and attach a log sheet describing the individual shipments documented on the tracking form.

Transporters may consolidate individual shipments of less than 220 pounds by initiating a new tracking form with combined total quantity information. They must then attach a log sheet describing the individual shipments that comprise the combined load.

Notifying EPA and the State

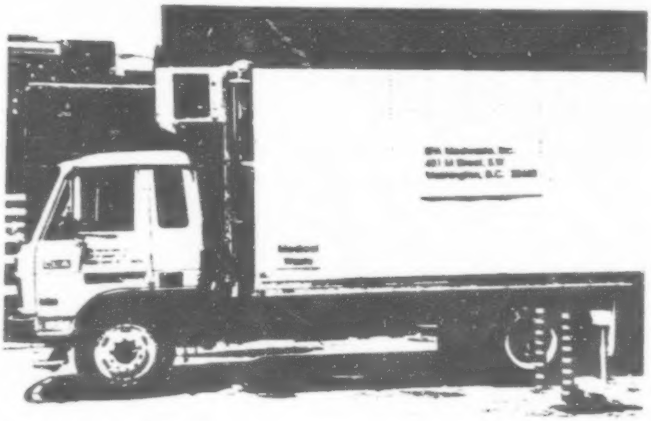
Transporters must notify both the EPA and the participating state before handling regulated medical wastes. If transporters plan to handle waste from more than one participating state, they must submit separate notification forms for each of those states. Transporters are required to send the original and one copy of each notification to EPA; another copy of the transporter notification must be sent to the director of the waste management agency in the participating state the transporter is notifying (see Appendix A). Appendix C includes a transporter notification form and instructions for notifying EPA and the state.

EPA will assign each transporter that notifies the Agency an EPA Medical Waste Identification Number. After receiving this number, transporters must enter it on the tracking form in either Box 5 or 17, as required (see Figure 1).

Vehicle Requirements

Vehicles used to transport regulated medical waste must

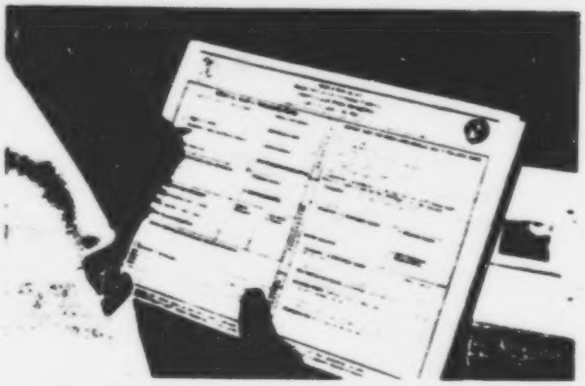
- have a fully enclosed, leak-resistant, cargo-carrying body, such as a cargo compartment, box trailer, or roll-off box.
- protect waste from mechanical stress or compaction.
- have a cargo-carrying body that is in good sanitary condition and that can be locked.
- have the following identification on the two sides and back of the cargo-carrying body in letters at least three inches high: name of the transporter; transporter's state permit or license number, if any; the words MEDICAL WASTE, REGULATED MEDICAL WASTE, or INFECTIOUS WASTE.



Vehicle identified as a transporter of medical waste

Tracking Medical Waste

The tracking form ensures that the transfer of each shipment of regulated medical waste is documented and reaches its destination. Therefore, it is crucial for every transporter to comply with tracking form requirements.



Transporter filling out a tracking form

Obtaining Forms

Transporters are responsible for providing the generator with the proper form when waste is destined for a disposal site in another participating state. In addition, they may assist generators by acquiring the appropriate forms based on the following hierarchy:

- from the participating state to which the waste is to be ultimately delivered. In this case, the transporter is required to provide tracking forms.
- if that state does not provide tracking forms, from the state in which the waste was generated.
- if the generator state does not print the tracking form, from other sources including reproduction of Figure 1 from this booklet or 40 CFR Part 259, Appendix I.

Accepting Waste Shipments

Transporters may not accept a shipment from a generator of more than 50 pounds a month unless the shipment is accompanied by a completed tracking form signed by the generator. Figure 3 diagrams the tracking system for transporters.

Transporters may not accept shipments of less than 50 pounds from facilities generating less than 50 pounds a month unless the material has been logged. Logged shipments, however, may only be accepted from the original generators, not from a transporter.

Before accepting for transport any regulated medical waste that is accompanied by a tracking form, the transporter must

- ensure that the waste is properly packaged, labeled, and marked (see Appendix B).
- certify that the tracking form accurately reflects the number and total weight of the packages.

Then the transporter must

- sign and date the tracking form, indicating acceptance of and responsibility for the regulated medical waste.
- return a signed copy of the tracking form to the generator before leaving the generator site.
- be sure that the tracking form remains with the regulated medical waste while in transit.

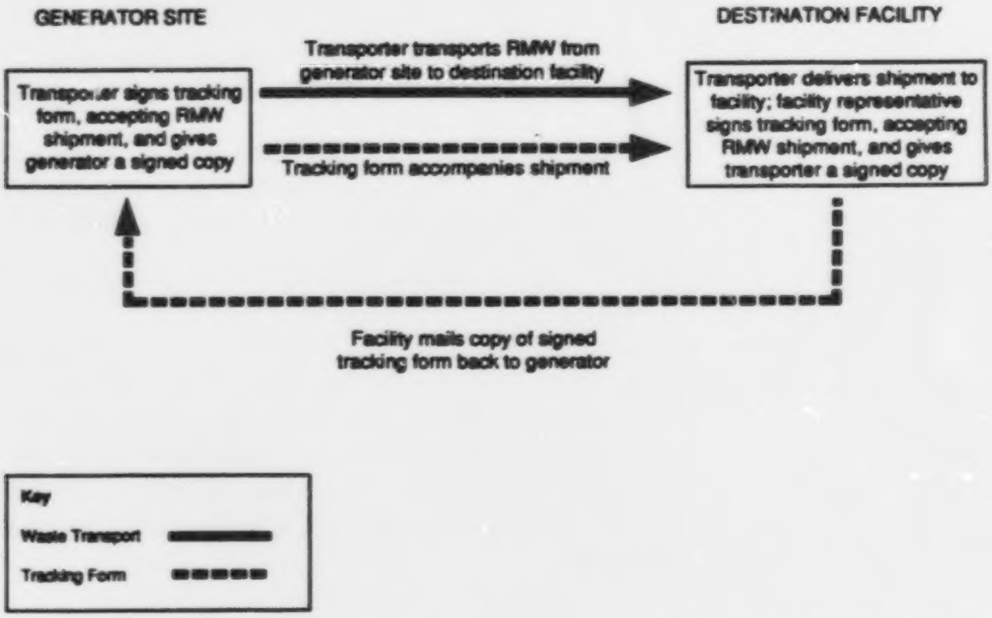
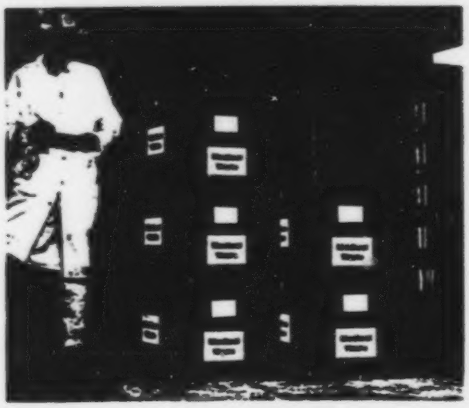
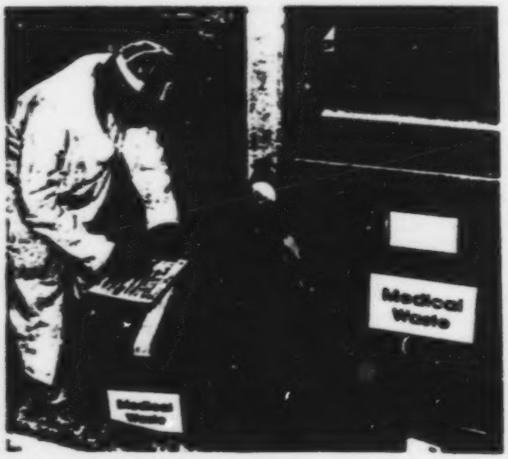

GENERATOR SITE
DESTINATION FACILITY
Transporter signs tracking form, accepting RMW shipment, and gives generator a signed copy
Transporter transports RMW from generator site to destination facility
Tracking form accompanies shipment
Transporter delivers shipment to facility; facility representative signs tracking form, accepting RMW shipment, and gives transporter a signed copy
Facility mails copy of signed tracking form back to generator
Key
Waste Transport
Tracking Form

FIGURE 3. Shipping regulated medical waste accompanied by a tracking form.



Transporter inspecting shipment of medical waste


Medical Waste
Medical Waste

Signing tracking form accepting waste shipment

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Delivering in the United States

The transporter must deliver the entire shipment to the next transporter, intermediate handler, or destination facility specified on the tracking form. If the waste cannot be delivered, the transporter must contact the generator for further instructions, revise the tracking form according to instructions, and deliver the entire shipment according to the generator's revised instructions.

Upon delivery of the waste to another transporter, intermediate handler, or destination facility located in the United States, the transporter must

- obtain the date of delivery and the handwritten signature on the tracking form of that transporter or the owner or operator of the facility.
- retain one copy of the signed and dated tracking form.
- give the remaining copies of the tracking form to the accepting transporter, intermediate handler, or destination facility.

Delivering Outside the United States

When transporting regulated medical waste across an international border or delivering to a transporter, intermediate handler, or destination facility located in a foreign country, such as Canada, the transporter must

- sign the tracking form and verify that the waste has been delivered.
- retain one copy of the signed tracking form.
- return all remaining copies of the tracking form, by mail, to the generator.

Consolidating Shipments

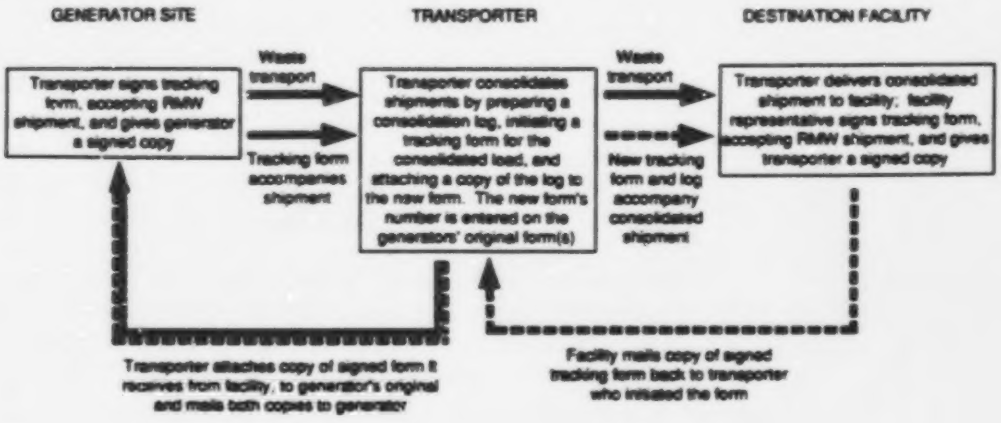
Transporters may consolidate multiple shipments of less than 220 pounds and issue a new tracking form, making the transporter the tracking form initiator (see Figure 4). The transporter, in effect, becomes the generator of the combined shipment and must follow the pre-transporting procedures. Transporters consolidating shipments must maintain a consolidation log that lists all shipments combined on the new tracking form. A copy of this log accompanies the tracking form to the destination facility and includes the

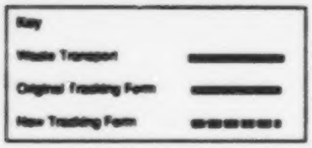
onsolidating tracking forms

- name of each generator.
- generator state permit or identification number. If the generator state does not issue permit or identification numbers, then the generator address.
- date the regulated waste was originally shipped by the generator.
- quantity of each category of regulated medical waste (number of containers and/or weight in pounds) shipped by each generator.
- names and state permit or identification numbers of all previous transporters or, if identification numbers are not available, then the transporters' addresses.

If the waste was accompanied by a tracking form initiated by the original generator, the transporter holds this form until receiving the signed form indicating the waste was accepted for disposal. The transporter retains a copy of both forms, then attaches copies of both forms together and sends them, within 15 days, to the original generator. In this way, the generator knows that the waste was accepted for disposal. If a transporter consolidates or remanifests shipments, the transporter must also comply with Exception Reporting requirements.

Consolidating shipments of less than 50 pounds


GENERATOR SITE
TRANSPORTER
DESTINATION FACILITY
Transporter signs tracking form, accepting RMW shipment, and gives generator a signed copy
Waste transport
Tracking form accompanies shipment
Transporter consolidates shipments by preparing a consolidation log, initiating a tracking form for the consolidated load, and attaching a copy of the log to the new form. The new form's number is entered on the generators' original form(s)
Waste transport
New tracking form and log accompany consolidated shipment
Transporter delivers consolidated shipment to facility; facility representative signs tracking form, accepting RMW shipment, and gives transporter a signed copy
Transporter attaches copy of signed form it receives from facility, to generator's original and mails both copies to generator
Facility mails copy of signed tracking form back to transporter who initiated the form


Key
Waste Transport
Original Tracking Form
New Tracking Form

The flow charts above illustrate the movement of the tracking form for consolidated shipments of regulated medical waste. The top diagram shows the documentation process for consolidation of shipments of less than 50 pounds, which are accepted by the transporter unaccompanied by a tracking form. The bottom diagram shows the documentation process for consolidating, or remanifesting, shipments of less than 220 pounds, which are accompanied by tracking forms initiated by the original generator.

Consolidating/remanifesting shipments of less than 220 pounds

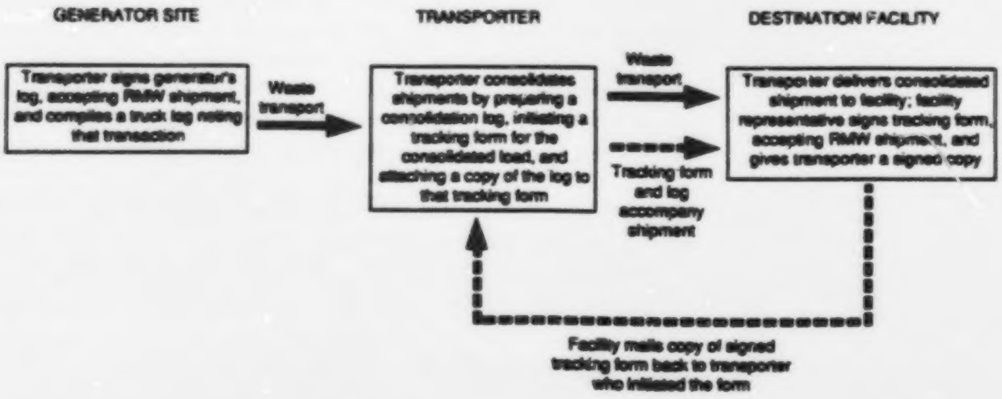

GENERATOR SITE
TRANSPORTER
DESTINATION FACILITY
Transporter signs generator's log, accepting RMW shipment, and compiles a truck log noting that transaction
Waste transport
Transporter consolidates shipments by preparing a consolidation log, initiating a tracking form for the consolidated load, and attaching a copy of the log to that tracking form
Waste transport
Tracking form and log accompany shipment
Transporter delivers consolidated shipment to facility; facility representative signs tracking form, accepting RMW shipment, and gives transporter a signed copy
Facility mails copy of signed tracking form back to transporter who initiated the form

FIGURE 4. Consolidating shipments

Rail Shipments of Regulated Medical Waste

In those instances where regulated medical wastes generated in a participating state are transported by rail, special rules apply. For further information see 40 CFR Part 259, Subpart J. Rail shippers accepting regulated medical waste from a non-rail transporter must

- sign and date the tracking form, acknowledging acceptance of the regulated medical waste.
- return a signed copy of the tracking form to the transporter.
- forward at least three copies of the tracking form to the next non-rail transporter, if any; or to the intermediate handler or destination facility, if the shipment is delivered to that facility by rail; or to the last rail transporter designated to handle the waste in the United States.
- ensure that the load is accompanied by shipping papers containing all tracking form information, except permit or license numbers and generator certification.
- retain one copy of the tracking form or rail shipping papers.

Recordkeeping

Transporters are required to keep for three years copies of all tracking forms; transporter logs; Exception and Discrepancy Reports, if filed; and semi-annual reports. In addition, for waste accompanied by a tracking form and consolidated by the transporter onto another tracking form, the transporter must also retain for three years

- the transporter copy of the generator-initiated tracking form.
- a copy of the transporter-initiated consolidation tracking form signed by the intermediate handler or destination facility.
- a copy of each required transporter report, described below.

Reporting

Transporters must submit reports every six months for the two-year duration of the program, as well as Exception and Discrepancy Reports, if necessary.

Transporter Reports

If a transporter accepts regulated medical waste directly from a generator in a participating state or transports waste generated in a participating state during the six-month reporting period, the transporter must submit a report summarizing those activities for each state. These reports must be submitted to the chief of the EPA Waste Characterization Branch and the director of the waste management agency in the affected state. Each report contains information about the transporter, each generator from which waste was accepted, and each facility to which waste was delivered.

Reports are due on the 45th day following the end of the six-month reporting period, summarizing information from tracking forms and transporter logs. For further information, refer to 40 CFR Part 259, Appendix III. For copies of the form call the RCRA Hotline at (800) 424-9346; in Washington, D.C., call 382-3000.

Exception Reports

Transporters who have initiated a tracking form must also meet the Exception Reporting requirements of the tracking program. If a signed tracking form bearing the signature of the disposal facility representative is not received within 35 days from the date the regulated medical waste was accepted from the original generator, the initiator of the tracking form must try to locate the waste. If, after 45 days, a signed tracking form is still not received, then an Exception Report must be filed by the transporter with the state and the EPA Regional Administrator on day 46. The Exception Report consists of a letter describing the efforts and the results of such efforts to determine the disposition of the waste and a legible copy of the original tracking form. A copy of this report is to be retained for three years.

Discrepancy Reports

Transporters are generally not required to file Discrepancy Reports. However, if a transporter learns after accepting waste that there is a discrepancy, the transporter should try to resolve the problem. A discrepancy exists if a tracking form indicates a difference between the waste that is accepted and that which is documented on the accompanying tracking form. For example, the number of containers or the waste categories might be inconsistent or the package might leak. Other types of discrepancies include the presence of broken, torn, or leaking packaging; waste unaccompanied by a tracking form, where one is required; or an incomplete or improperly completed tracking form. If such discrepancies are discovered and they cannot be resolved, they must be reported in writing within 15 days to the appropriate EPA Regional Administrator and the generator's state agency. A legible copy of the tracking form or shipping papers is to be attached. Discrepancy Reports must be retained for three years.

Additional Reports

The Administrator may require transporters to furnish additional information concerning the quantities and management methods of regulated medical waste.

Regulated Medical Waste Transporter Checklist

Do these regulations apply to you?

______ Does your company participate, or intend to participate, in the transport of medical wastes?

______ Does your company intend to continue or initiate such activities for medical wastes that have been generated in one of the following states: Connecticut, New Jersey, New York, Rhode Island and Puerto Rico?

Is your company authorized to transport regulated medical waste?

______ Has your company submitted the following notification information to the Waste Characterization Branch, EPA Headquarters for each participating state that may be a source of medical waste you will handle?

- ______ Company name, mailing address and EPA Hazardous Waste Identification Number (if applicable).
- ______ Name, address, and telephone number for each site in that state from which medical waste transport vehicles will operate.
- ______ State identification or permit number(s), if applicable, required for handling medical or infectious waste.
- ______ Statement signed by a corporate official or owner or operator: "I certify, under penalty of criminal or civil prosecution for the making or submission of false statements, representations, or omissions, that I have read, understand and will comply with the regulations at 40 CFR Part 259, issued under authority of Subtitle J of the Resource Conservation and Recovery Act."

______ Have you provided the appropriate waste management agency in each of those participating states with a copy of the EPA notification for that state?

______ Has your company received a unique EPA-assigned Medical Waste Identification Number?

______ Are you entering your Medical Waste Identification Number as required on the Tracking Form?

______ Do individual states in which you handle or transport regulated medical waste require other licensing or permitting requirements that may affect your company's medical waste transportation activities?

Does your company ensure that the following requirements are met for all its vehicles that transport regulated medical wastes?

______ The cargo-carrying body (i.e., cargo compartment, boxtrailer, roll-off box, freight container) is fully enclosed, leak resistant, and capable of being locked.

______ The cargo-carrying body is maintained in good, sanitary condition.

______ The cargo-carrying body is secured and locked if the vehicle is left unattended.

______ The vehicles have the following identification information on both sides and rear of the cargo-carrying body, in letters at least 3 inches in height:
(1) Company name
(2) Company's state permit or license number, if state issues and requires one, or else company's address
(3) The words MEDICAL WASTE, INFECTIOUS WASTE, or REGULATED MEDICAL WASTE

______ Waste is not subjected to mechanical stress or compaction during loading and unloading, or during transit.

______ Regulated medical waste is not transported in the same container as other solid waste unless the combined material is to be managed as regulated medical waste.

Does your company manage transportation of regulated medical wastes in accordance with all applicable regulations, including

______ Ensuring that all accepted shipments of regulated medical waste are properly labeled, marked, and accompanied by proper paperwork?

______ Ensuring that all shipments, except for those of less than 50 pounds which are from generators of less than 50 pounds per month, are accompanied by a properly completed Tracking Form?

Do you

______ Ensure that the generator is provided with the proper Tracking Form if the waste is to be disposed of in another participating state?

______ Ensure that the Tracking Form is properly completed and that the information on the form accurately represents the number and/or total weight and waste classification of the packages being accepted for transport?

______ Make sure generator provides information on designated treatment or disposal facility before signing the form?

______ Visually inspect all packages of regulated medical waste to be accepted for transport to ensure they are properly packaged, labeled, and marked?

______ Ensure that the "Generator Certification" block has been signed by an authorized representative of the generator facility before accepting that shipment?

______ Sign and date the Tracking Form, acknowledging acceptance of the waste from the generator and return the generator's copy before leaving the generator's premises?

______ Ensure that the Tracking Form accompanies the waste it covers at all times during transport?

When delivering waste to another authorized transporter, intermediate handler, or destination facility, do you

______ Make certain all regulated medical waste documented on the accompanying form is transferred to the next party and, if any discrepancies are apparent, attempt to resolve them with the recipient of the documented waste (i.e., counting containers, reviewing all relevant logsheets, etc.)?

______ Obtain the signature and acceptance date from an authorized representative of that party?

______ Retain the transporter's copy of the Tracking Form signed by the receiving party?

______ Give the remaining copies of the completed Tracking Form to the accepting transporter, transfer or treatment or disposal facility?

When consolidating regulated medical waste shipments of 50 to 220 pounds onto a single Tracking Form prior to transferral to another transporter, intermediate handler, or destination facility, do you

______ Complete the Tracking Form as both generator and initial transporter, signing both certification blocks (blocks 1 through 16)?

______ Record in a transporter's log the following information for all loads that are being consolidated onto the single Tracking Form?

    ______ Names of generators

    ______ Generators' addresses or unique identification numbers

    ______ Original Tracking Form number(s) or dates waste was originally accepted from generators

    ______ Quantity of waste by waste type (treated, untreated, or state-regulated), by number of containers and/or weight in pounds, from each generator

    ______ New Tracking Form number that covers consolidated waste

______ Attach a copy of the transporter's log sheet to the new Tracking Form?

______ Attempt to resolve any apparent discrepancies with the recipient of the documented waste (i.e., recounting containers, reviewing all relevant logsheets, etc.)?

______ Obtain the signature and acceptance date from an authorized representative of the receiving transporter or facility?

______ Retain the generator's and transporter's copies of the completed Tracking Form for recordkeeping?

______ Give the remaining copies of the completed Tracking Form to the authorized recipient (accepting transporter, intermediate handler or destination facility)?

______ Within 15 days of receipt of the treatment/disposal facility-signed Tracking Forms that you initiated, attach a copy to the generator's original form and return both copies to the generator(s)?

When handling shipments of less than 50 pounds of regulated medical waste from generators of less than 50 pounds per month, which are documented through use of logs, do you

______ Ensure that all regulated medical waste to be accepted for transport is properly packaged, labeled, and marked?

______ Sign and date the generator's log, which contains the shipment information (transporter name, state identification number or address, and quantity of waste shipped), after determining that information is accurate?

______ Record in your transporter's log the following information?

    ______ Names of generators

    ______ Generators' addresses or unique identification numbers

    ______ Date waste was originally accepted from generators

    ______ Quantity of waste by waste type (untreated, treated or state regulated), by number of containers and weight in pounds, from each generator

______ Before transfer of the "logged" waste to the next authorized party, initiate a Tracking Form which will account for all consignments of logged materials which are on board the vehicle? Do you fill out the form as both "Generator" and "Transporter," signing both certification blocks (blocks 1 through 16)?

______ Attach a copy of the appropriate log sheet(s) to the completed Tracking Form?

When delivering the waste to another authorized transporter, intermediate handler, or destination facility, do you

______ Make certain all material documented on the accompanying form is transferred to the next party? If any discrepancies are apparent, do you attempt to resolve them with the recipient of the documented waste (i.e., recounting containers, reviewing all relevant logsheets, etc.)?

______ Obtain the signature and acceptance date from an authorized representative of the party accepting the waste?

______ Retain both the generator's and transporter's copy of the signed Tracking Form for recordkeeping?

______ Give the remaining copies of the completed Tracking Form to the authorized recipient?

Do you understand the following recordkeeping requirements?

______ Transporters must maintain records of all transactions involving regulated medical waste handled for a period of 3 years from the date it accepts such waste.

______ Records must include copies of

  ______ Generator-initiated Tracking Forms signed by company employees.

  ______ Tracking Forms your company has initiated for consolidation of shipments or documentation of "small quantity" logged waste.

  ______ Transporter's log information recorded for all small quantity logged shipments and consolidation transactions.

  ______ Reports submitted by your company including Exception, Discrepancy, and Transporter (semi-annual) Reports.

Do you understand that

______ Transporter Reports documenting your waste handling activities are required?

______ Transporters may be required to file Exception Reports and, if a discrepancy is discovered after accepting waste, a Discrepancy Report?

______ The Administrator may require transporters to provide additional information, if deemed necessary?

Glossary

Following are the classes of regulated medical wastes and a description of each.

Cultures and Stocks	Cultures and stocks of infectious agents and associated biologicals including: cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.
Pathological Wastes	Human pathological wastes, including tissues, organs, and body parts and body fluids that are removed during surgery or autopsy or other medical procedures, and specimens of body fluids and their containers.
Human Blood and Blood Products	Liquid waste human blood; products of blood; items saturated and/or dripping with human blood; or items that were saturated and/or dripping with human blood that are now caked with dried human blood including serum, plasma, and other blood components, and their containers, which were used or intended for use in either patient care, testing and laboratory analysis, or the development of pharmaceuticals. Intravenous bags are also included in this category.
Sharps	Sharps that have been used in animal or human patient care or treatment or in medical, research, or industrial laboratories. These include hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.
Animal Waste	Contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals, or testing of pharmaceuticals.
Isolation Wastes	Biological waste and discarded materials contaminated with blood, excretion, exudates, or secretions from humans who are isolated to protect others from certain highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.
Unused Sharps	The following unused, discarded sharps: hypodermic needles, suture needles, syringes, and scalpel blades.

The following terms are defined here to address the management of medical wastes. They may be different from those federal definitions used for solid or hazardous waste.

Biologicals	Preparations made from living organisms and their products, including vaccines, cultures, etc. intended for use in diagnosing, immunizing, or treating humans or animals, or in related research.
Blood Products	Any product derived from human blood, including but not limited to blood plasma, platelets, red or white blood corpuscles, and other derived licensed products, such as interferon.
Body Fluids	Liquid emanating or derived from humans and limited to blood; cerebrospinal, synovial, pleural, peritoneal, and pericardial fluids; and semen and vaginal secretions.
Central Collection Point	A location where a generator consolidates regulated medical waste brought together from original generation points prior to its transport off-site or its treatment on-site.
Container	Any portable device in which a material is stored, transported, disposed of, or otherwise handled. The term container, when describing the packaging requirements, does not include items that are regulated medical waste
Decontamination	The process of reducing or eliminating the presence of harmful substances, such as infectious agents, so as to reduce the likelihood of disease transmission from those substances.
Destination Facility	The disposal facility, the incineration facility, or the facility that both treats and destroys regulated medical waste to which medical wastes are shipped.
Destroyed Regulated Medical Waste	Regulated medical waste that has been ruined, torn apart, or mutilated through processes such as thermal treatment, melting, shredding, grinding, tearing, or breaking, so that it is no longer generally recognizable as medical waste, but has not yet been treated. It does not mean compacted regulated medical waste.

Destruction Facility	A facility that destroys regulated medical waste by ruining or mutilating it, or tearing it apart.
Facility	All contiguous land and structures, other appurtenances, and improvements on the land used for treating, destroying, storing, or disposing of regulated medical waste. A facility may consist of several treatment, destruction, storage, or disposal operational units.
Generator	Any person, by site, whose act or process produces regulated medical waste or whose act first causes a regulated medical waste to become subject to regulation. In the case where more than one person (e.g., doctors with separate medical practices) is located in the same building, each individual business entity is a separate generator. [Note: see definition of "person."]
Infectious Agent	Any organism (such as a virus or a bacteria) that is capable of being communicated by invasion and multiplication in body tissues and capable of causing disease or adverse health impacts in humans.
Intermediate Handler	A facility that either treats regulated medical waste or destroys regulated medical waste but does not do both. The term does not include transporters.
Laboratory	Any research, analytical, or clinical facility that performs health care-related analysis or service. This includes medical, pathological, pharmaceutical, and other research, commercial, or industrial laboratories.
Landfill	A disposal facility or part of a facility where regulated medical waste is placed in or on the land and which is not a land treatment facility, a surface impoundment, or an injection well.
Medical Waste	Any solid waste which is generated in the diagnosis, treatment (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. The term does not include any hazardous waste identified or listed under 40 CFR Part 261 or any household waste as defined in 40 CFR §261.4(b)(1).
On-site	The same or geographically contiguous property which may be divided by public or private right of way, provided the entrance and exit between the properties is at a crossroads intersection, and access is by crossing as opposed to going along the right of way. Non-contiguous properties owned by the same person but connected by a right of way which he controls and to which the public does not have access is also considered on-site property.
Original Generation Point	Location where regulated medical waste first becomes waste (is "generated").
Oversized Regulated Medical Waste	Medical waste that is too large to be placed in plastic bags or standard containers.
Package or Outside Package	The packaging/container and its contents.
Packaging	The assembly of one or more containers and any other components necessary to assure minimum compliance with the program's packaging requirements.
Person	An individual, trust, firm, joint stock company, corporation (including a government corporation), partnership, association, state, municipality, commission, political subdivision of a state, any interstate body, or any department, agency or instrumentality of the United States.
Storage	The temporary holding of regulated medical wastes at a designated accumulation area before treatment, disposal, or transport to another location.
Transfer Facility	Any transportation-related facility including loading docks, parking areas, storage areas and other similar areas where shipments of regulated medical waste are held during the course of transportation. Also, a location in which medical waste is transferred between two vehicles.
Treated Regulated Medical Waste	Regulated medical waste that has been treated to substantially reduce or eliminate its potential for causing disease, but that has not yet been destroyed.
Treatment	When used to refer to waste handling, it means any method, technique, or process designed to change the biological character or composition of any regulated medical waste so as to substantially reduce or eliminate its potential for causing disease.

Appendix A

EPA Regional Offices and Participating State Programs

Participating State Programs

Connecticut Department of
Environmental Protection
Solid Waste Management Unit
State Office Building
165 Capitol Avenue
Hartford, CT 06106
(203) 566-5847
(Region I)

New Jersey Department of
Environmental Protection
Division of Solid Waste Management
401 East State Street, CN 414
Trenton, NJ 08625
(609) 984-7840
(Region II)

New York State Department of
Environmental Conservation
50 Wolf Road
Albany, NY 12233
Tracking form: (518) 485-8394
Other inquiries: (518) 457-3254
(Region II)

Rhode Island Department of
Environmental Management
9 Hayes Street
Providence, RI 02907-5003
(401) 277-2771
(Region I)

Puerto Rico Environmental
Quality Board
Box 11488
Santurce, PR 00910
(809) 722-0439
(Region II)

EPA Regional Offices

Region I
State Waste Programs
Branch
JFK Federal Building
Boston, MA 02203
(617) 573-5758

Region II
Air and Waste
Management Division
26 Federal Plaza
New York, NY 10278
(212) 264-5166

Caribbean Field Office
(809) 729-6920

Region III
Waste Management
Branch
841 Chestnut Building
Philadelphia, PA 19107
(215) 597-2842

Region IV
Hazardous Waste
Management Division
345 Courtland Street, N.E.
Atlanta, GA 30365
(404) 347-3016

Region V
RCRA Activities
230 S. Dearborn Street
Chicago, IL 60604
(312) 353-9510

Region VI
Air and Hazardous Materials
Division
1445 Ross Avenue
Suite 1200
Dallas, TX 75270
(214) 655-6652

Region VII
RCRA Branch
726 Minnesota Avenue
Kansas City, KS 66101
(913) 236-2856

Region VIII
Waste Management Division
999 18th Street, Suite 500
Denver, CO 80202
(303) 293-1496

Region IX
Toxics and Waste
Management
215 Fremont Street
San Francisco, CA 94105
(415) 974-8388

Region X
Waste Management Branch
1200 Sixth Avenue
Seattle, WA 98101
(206) 442-6501

Appendix B Packaging, Labeling, and Marking Requirements

Transporters may not accept any regulated medical waste generated in a participating state unless the waste is properly packaged, labeled, and marked. However, transporters may offer to prepare wastes for shipping as a service to generators, following the pre-transporting requirements below.

Packaging Medical Wastes

All regulated medical wastes must be placed in a container or combination of containers that are rigid and leak resistant, impervious to moisture, strong enough to prevent tearing or bursting under normal handling, and sealed securely. Often generators place medical waste other than sharps or fluids into plastic bags; the transporter then puts the bags into a box.

Sharps and fluids may also be boxed by the transporter. But first sharps, such as needles and scalpels, must be packaged in a rigid container resistant to punctures; fluids must be poured into a container resistant to breaking and equipped with a tightly fitting stopper or lid.

Oversized medical waste—animal carcasses and other items too large for standard bags and containers—should be handled and transported, minimizing contact with transportation workers, other handlers, and the public.

Non-rigid packaging and inner liners, such as plastic bags, are likely to become contaminated through use. Therefore, they are considered regulated medical waste and may not be reused. Rigid containers, including bins, barrels, and boxes can be reused, but must be made free of any visible contamination. If rigid containers cannot be cleansed of visible contamination, then they too are handled as regulated medical wastes.

Labeling

To alert handlers, a water-resistant label must be affixed to all packaging, or containers, of untreated wastes. When there is inner and outer packaging, each container of waste must be labeled INFECTIOUS WASTE or MEDICAL WASTE or display the universal biohazard symbol. Red plastic bags, when used as inner packaging for untreated wastes, need no labels. However, the outer packaging must still carry the proper label or symbol. Treated medical wastes do not require such warning labels, but must be marked as specified below.

Marking

Before shipment, all packaging—inner and outer—must be marked with indelible ink or with a water-resistant identification tag. Each inner container, if used, must show the name and identifying numbers or address of the generator. Each outer container must identify the contents as medical waste and include the information as shown on the sample tag below.

If more than one transporter handles the waste, each subsequent transporter must attach its own identification without obscuring any existing markings. The transporter taking possession of a shipment must ensure that the marking tag also contains the following information.

- name of transporter receiving the waste shipment.
- transporter state permit or identification number. (If the state does not issue these numbers, transporter address.)
- date of receipt of the regulated medical waste.

General Information:

AUTHORITY:
This information is required by the EPA under authority of Section 11003 and 11004 of the Resource Conservation and Recovery Act.

WHO MUST NOTIFY:
Transporters who transport regulated medical waste that is generated in a Covered State must notify the U.S. Environmental Protection Agency for each Covered State's regulated medical waste they intend to transport. This requirement extends to transporters who do not actually transport the waste within that Covered State's boundaries but who transport the waste, generated in the Covered State, outside that Covered State's boundaries.

Transporters planning such activity may either complete a Notification Form or submit a letter containing the information required in 40 CFR 259.72(b). EPA will then issue a Medical Waste Identification Number unique to that transporter for each Covered State for which they are notifying. That number will be used to identify regulated medical waste transporters and can be used by generators to verify that the transporter has notified EPA of his intent to transport waste from their Covered State.

WHEN TO NOTIFY:
Notification must be submitted for a Covered State before the transporter may accept regulated medical waste generated in that Covered State. Transporters may, however, accept such waste once they have submitted their notification, but before receiving their identification number. Upon receipt of that number, the transporter must enter it in Box 5 of the Medical Waste Tracking Form, when that form is required. Additionally, the transporter must enter that number in Box 17 of the Tracking Form when acting as a secondary transporter, and in Box 1 when initiating a tracking form for load consolidation purposes.

WHERE TO SEND NOTIFICATION:
Two copies of the completed Notification Form, for each Covered State, must be sent to:
Chief, Waste Characterization Branch
Environmental Protection Agency (OS-332)
401 M Street, S.W.
Washington, D.C. 20460

One copy must also be sent to the Director of the waste management agency in the State for which the transporter is notifying.

NOTIFICATION FORM INSTRUCTIONS:
Note: All information must be typed or printed clearly.

Box 1. Covered State for which you are notifying. Enter the name of the Covered State of origin of the regulated medical waste(s) you intend to collect and/or transport. Enter only one State in this space; if you intend to transport waste from more than one Covered State you must submit a seperate Notification Form for each of those States.

Box 2. Transporter Name and Mailing Address. Enter your organization's name, mailing address, the name of a contact person at that location who is knowledgeable about your operations, and include that person's telephone number.

Box 3. EPA Hazardous Waste Identification Numbers. If the facility identified in Box 2 has an EPA Hazardous Waste Identification Number, enter the EPA-assigned 12-character hazardous waste identification number for the facility.

Box 4. Transporter's Facility Location(s). Enter the address, facility telephone number, and any current State medical or infectious waste permit or license numbers for each transportation or transfer facility located within the Covered State identified in Box 1. If there are more than four such facilities in that Covered State you will need to use an additional sheet(s) to provide the required facility information; attach the additional sheets to the first.

Box 5. Certification. The Certification Statement must be read and hand signed by a corporate officer or the owner/operator of the transporter company.

United States
Environmental Protection
Agency

Medical WasteTransporter Notification Form

FOR OFFICIAL EPA USE ONLY
Identification No.: | | | | | | | | | | | | |
Date Received: | |
Receiving Official:

(Please Type or Print Clearly)

1. **Covered State for which you are notifying**

2. **Transporter Name and Mailing Address**

Name

Address

City State Zip Code

Contact Area Code/Telephone Number

3. **EPA Hazardous Waste ID Number**

| | | | | | | | | | | | |

(The ID number entered should be for the facility identified in Box 2)

4. **Transporter's Facility Location(s)** *(use additional sheets if necessary)*

Address

City State Zip Code

Area Code/ Telephone Number

Any current State Identification number(s) (permit or license) required to handle medical or infectious waste

Address

City State Zip Code

Area Code/ Telephone Number

Any current State Identification number(s) (permit or license) required to handle medical or infectious waste

Address

City State Zip Code

Area Code/ Telephone Number

Any current State Identification number(s) (permit or license) required to handle medical or infectious waste

Address

City State Zip Code

Area Code/ Telephone Number

Any current State Identification number(s) (permit or license) required to handle medical or infectious waste

Address

City State Zip Code

Area Code/ Telephone Number

Any current State Identification number(s) (permit or license) required to handle medical or infectious waste

Address

City State Zip Code

Area Code/ Telephone Number

Any current State Identification number(s) (permit or license) required to handle medical or infectious waste

5. **Certification**

I certify, under penalty of criminal or civil prosecution for making or submission of false statements, representations or omissions, that I have read, understand, and will comply with the regulations at 40 CFR Part 259, issued under authority of Subtitle J of the Resource Conservation and Recovery Act.

Signature Title Date

United States
Environmental Protection
Agency

Solid Waste and
Emergency Response
(OS-305)

EPA/530-SW-89-023
September 1989

EPA

Managing and Tracking Medical Wastes

A Guide to the Federal Program for Treatment, Destruction, and Disposal Facilities

Printed on recycled paper.

Introduction

In response to the growing public concern over mismanagement of medical wastes, Congress enacted the *Medical Waste Tracking Act*.

The Act charges the Environmental Protection Agency with responsibility for implementing a two-year demonstration medical waste tracking program that will help determine the best medical waste management procedures for the future. The program's goal is to find an effective means to ensure that regulated medical wastes get from their point of generation to their point of disposal.

Generators of regulated medical wastes will be part of the new demonstration tracking program in the States of Connecticut, New Jersey, New York, and Rhode Island, and the Commonwealth of Puerto Rico. Transporters and facilities that store, treat, destroy, and dispose of these wastes will also be part of the program.

This guide offers general information about the tracking program (Section 1) and specific instructions for facilities that treat, destroy, or dispose of regulated medical waste (Section 2). Section 2 includes requirements for facilities that dispose of these wastes—destination facilities—and slightly different requirements for facilities that treat *or* destroy wastes—intermediate handlers. Separate guides in this series are provided for generators and transporters of regulated medical wastes.

This guide describes the federal program only. It is designed to help facilities that treat, destroy, or dispose of wastes generated in participating states comply with the program. For more complete information, facility owners and operators should refer to "Standards for the Tracking and Management of Medical Waste," interim final rule (40 CFR Part 259). In addition, states participating in the program have their own rules for managing medical waste. For further assistance, addresses and phone numbers of EPA Regional Offices are listed in Appendix A.

For additional copies of *Managing and Tracking Medical Wastes* or a copy of 40 CFR Part 259, call the RCRA Hotline at (800) 424-9346 or, in Washington, D.C., 382-3000.

The cooperation of all participants in the management of regulated medical waste will assure the success of this important demonstration program and reduce public exposure to the waste.

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Section 1: The Medical Waste Tracking Program

In response to public concern over the mismanagement of medical wastes, the *Medical Waste Tracking Act* was enacted in the fall of 1988. The law directs the Environmental Protection Agency (EPA) to establish a two-year demonstration program for tracking medical wastes.

Under this law, EPA has issued regulations entitled "Standards for the Tracking and Management of Medical Waste" (40 CFR Part 259). The regulations list the medical wastes to be tracked and cover standards for separating, packaging, and labeling medical wastes before sending them for treatment or disposal. The results of the demonstration program are intended to help determine whether such a program should be extended nationwide.

> **The *Medical Waste Tracking Act* amends the *Resource Conservation and Recovery Act* (RCRA) by adding Subtitle J. It defines medical waste as ". . . any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. . . ."**

Participating in the demonstration program are the States of Connecticut, New Jersey, New York, and Rhode Island, and the Commonwealth of Puerto Rico. The regulation is an interim final rule. It will be in effect for two years, until June 22, 1991. In Connecticut, New Jersey, and New York, the program is effective beginning June 22, 1989; in Rhode Island and the Commonwealth of Puerto Rico, the program is effective beginning July 24, 1989.

The demonstration program involves **only** regulated medical wastes **generated in one of the states** participating in the program, even when these wastes leave the state. The program sets up a system for tracking the waste from the generator to the disposal site. A tracking form that accompanies this waste is signed and a copy is retained by a representative of the waste generator and each transporter, transfer station, and treatment, destruction, and disposal facility handling it. When the final disposer—the destination facility—accepts the waste, a copy of the signed tracking form is returned to the generator. In this way the generator is assured that the waste was received for disposal. The tracking system includes "exception" and "discrepancy" reporting to alert EPA and the states if wastes are not being handled properly.

To minimize contact with regulated medical wastes by workers, handlers, and the public, the program includes specific requirements for segregating, packaging, labeling, marking, and storing medical wastes before they are shipped to another site for treatment, destruction, or disposal. Other requirements include recordkeeping, reporting, and enforcement. EPA will evaluate the success of the program and report the results to Congress.

Waste Managers Participation

This booklet is intended to help facilities that treat, destroy, or dispose of regulated medical wastes generated in the participating states comply with the federal rules. Facilities in these states must also follow rules required by the individual states. Owners and operators of facilities should check with their state officials for clarification of state rules. While participating states use the same basic tracking form as EPA's, some states might regulate more wastes or require special permits or licenses. Participating states are authorized to enforce this program.

The demonstration program includes medical waste generators in participating states; transporters of those wastes; and owners and operators of treatment, destruction, and disposal facilities that manage waste generated in participating states, even if their facilities are located in nonparticipating states. Similarly, the program includes transporters carrying regulated medical wastes from participating states, even if the wastes are then taken to nonparticipating states. The program includes vessels and transporters that take medical wastes to shore from ships docked in participating states. Federal facilities generating regulated medical wastes in participating states are also covered under this program.

Regulated Medical Wastes

Medical wastes affected by the pilot program include

- cultures and stocks of infectious agents.
- human blood and blood products.
- human pathological wastes, including those from surgery and autopsy.
- contaminated animal carcasses from medical research.
- wastes from patients isolated with highly communicable diseases.
- all used sharp implements, such as needles and scalpels, and certain unused sharps.

These regulated medical wastes fall into two categories: untreated or treated. The Glossary provides detailed descriptions of these medical wastes.

The demonstration program focuses on wastes that historically have been improperly managed and are most likely to pose a substantial threat to human health and the environment. However, any additional waste that a health care professional believes may pose a risk should be handled as a regulated medical waste.

Mixtures of regulated medical waste and general trash are regulated as medical waste. Mixtures of regulated medical waste and hazardous waste are usually regulated as hazardous waste. However, if medical waste is mixed with hazardous waste, which falls under the small quantity hazardous waste exemption, then the waste mixture must be tracked as medical waste under this program.

Pre-transporting Procedures

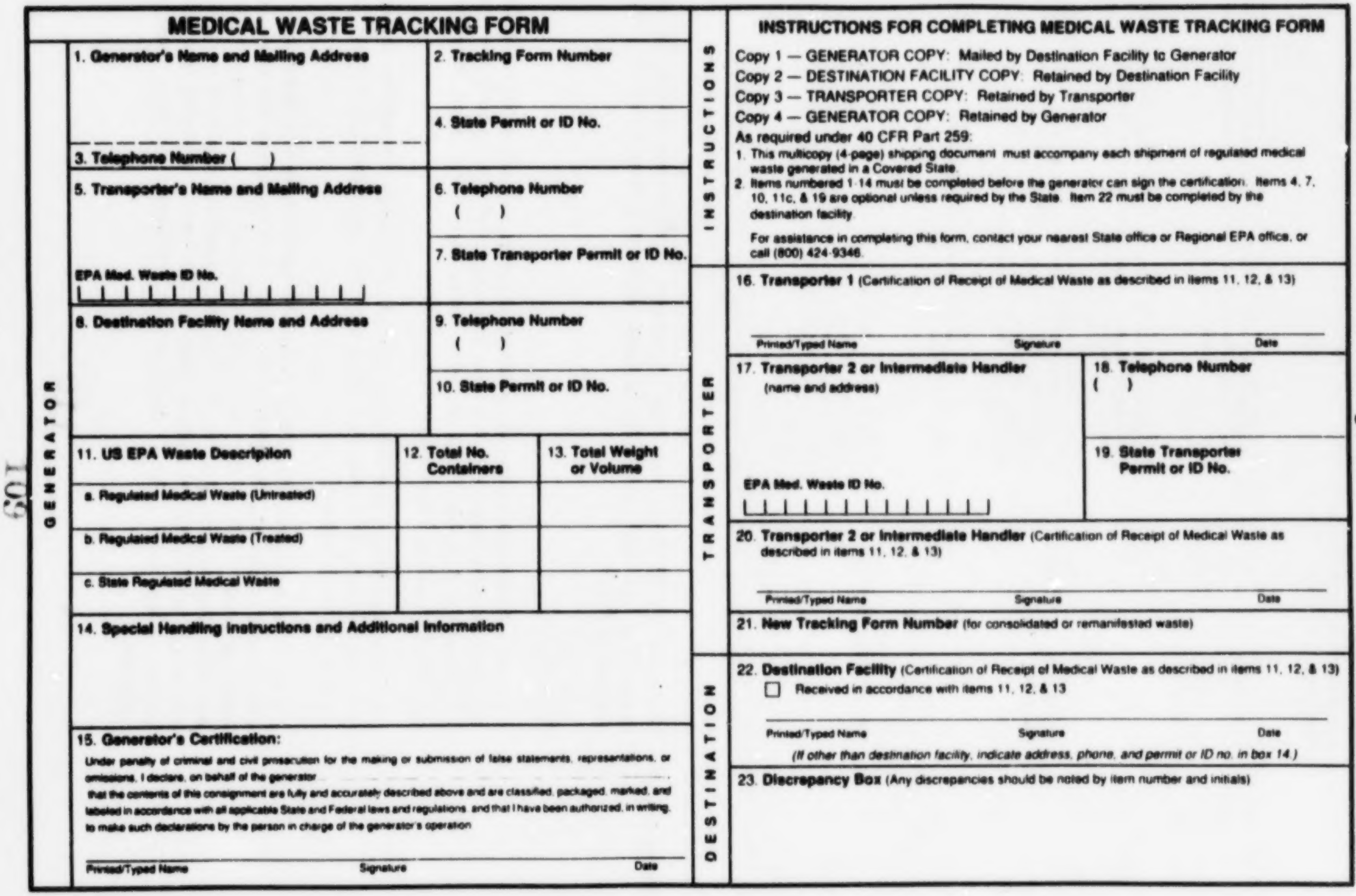
Regulated medical wastes that are to be transported to an off-site facility for treatment or disposal must be properly prepared for shipping. First, the wastes must be separated from general trash, and then sharp items, fluids, and other medical wastes must be separated from each other. They are then packaged to prevent tearing, breaking, or leaking during shipping and handling.

Packages are to be labeled and marked to identify the contents of the package and generator and transporter of the waste. In addition, stored wastes must be maintained to prevent them from coming into contact with workers or the public.

Tracking Regulated Medical Wastes

At the core of the medical waste demonstration tracking system is a MEDICAL WASTE TRACKING FORM (see Figure 1). This form must accompany each off-site shipment that weighs 50 pounds or more. Shipments from generators of less than 50 pounds a month may be combined onto one tracking form by the transporter. Generators, transporters, and treatment, destruction, and disposal facilities are responsible for filling in, forwarding, and retaining a copy of this form for their records. Figure 2 illustrates how the medical waste tracking system works.

FIGURE 1. Medical waste tracking form.



MEDICAL WASTE TRACKING FORM

GENERATOR

1. Generator's Name and Mailing Address

2. Tracking Form Number

3. Telephone Number (   )

4. State Permit or ID No.

5. Transporter's Name and Mailing Address

6. Telephone Number (   )

7. State Transporter Permit or ID No.

EPA Med. Waste ID No.

8. Destination Facility Name and Address

9. Telephone Number (   )

10. State Permit or ID No.

11. US EPA Waste Description	**12. Total No. Containers**	**13. Total Weight or Volume**
a. Regulated Medical Waste (Untreated)		
b. Regulated Medical Waste (Treated)		
c. State Regulated Medical Waste		

14. Special Handling Instructions and Additional Information

15. Generator's Certification:

Under penalty of criminal and civil prosecution for the making or submission of false statements, representations, or omissions, I declare, on behalf of the generator ______ that the contents of this consignment are fully and accurately described above and are classified, packaged, marked, and labeled in accordance with all applicable State and Federal laws and regulations, and that I have been authorized, in writing, to make such declarations by the person in charge of the generator's operation

Printed/Typed Name Signature Date

INSTRUCTIONS

INSTRUCTIONS FOR COMPLETING MEDICAL WASTE TRACKING FORM

Copy 1 — GENERATOR COPY: Mailed by Destination Facility to Generator
Copy 2 — DESTINATION FACILITY COPY: Retained by Destination Facility
Copy 3 — TRANSPORTER COPY: Retained by Transporter
Copy 4 — GENERATOR COPY: Retained by Generator

As required under 40 CFR Part 259:

1. This multicopy (4-page) shipping document must accompany each shipment of regulated medical waste generated in a Covered State.
2. Items numbered 1-14 must be completed before the generator can sign the certification. Items 4, 7, 10, 11c, & 19 are optional unless required by the State. Item 22 must be completed by the destination facility.

For assistance in completing this form, contact your nearest State office or Regional EPA office, or call (800) 424-9346.

TRANSPORTER

16. Transporter 1 (Certification of Receipt of Medical Waste as described in items 11, 12, & 13)

Printed/Typed Name Signature Date

17. Transporter 2 or Intermediate Handler (name and address)

EPA Med. Waste ID No.

18. Telephone Number (   )

19. State Transporter Permit or ID No.

20. Transporter 2 or Intermediate Handler (Certification of Receipt of Medical Waste as described in items 11, 12, & 13)

Printed/Typed Name Signature Date

21. New Tracking Form Number (for consolidated or remanifested waste)

DESTINATION

22. Destination Facility (Certification of Receipt of Medical Waste as described in items 11, 12, & 13)

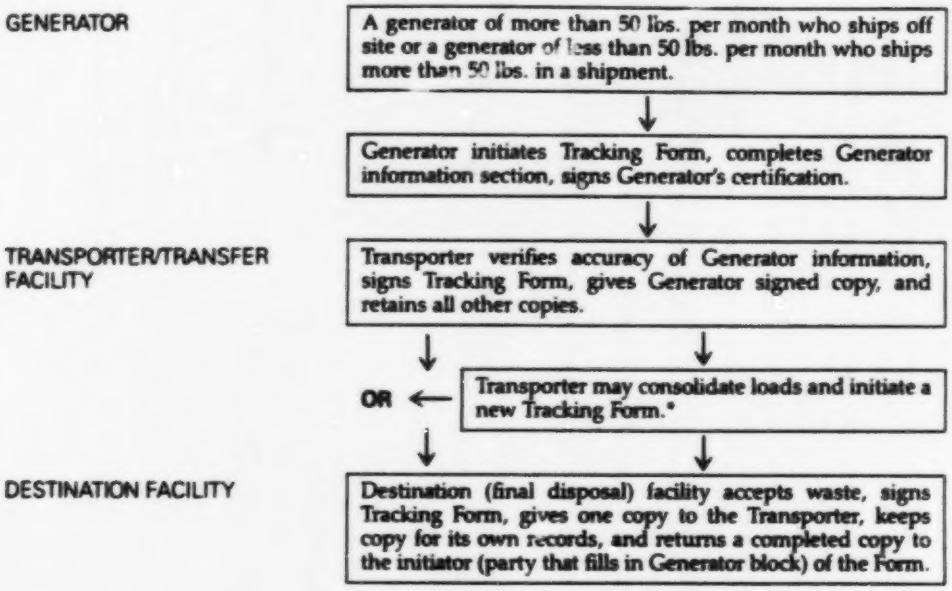
☐ Received in accordance with items 11, 12, & 13

Printed/Typed Name Signature Date

(If other than destination facility, indicate address, phone, and permit or ID no. in box 14.)

23. Discrepancy Box (Any discrepancies should be noted by item number and initials)

FIGURE 2. Medical waste tracking system. All medical waste shipments required to be accompanied by a tracking form are tracked from generator to final disposal, or destination facility.



A generator of more than 50 lbs. per month who ships off site or a generator of less than 50 lbs. per month who ships more than 50 lbs. in a shipment.

Generator initiates Tracking Form, completes Generator information section, signs Generator's certification.

Transporter verifies accuracy of Generator information, signs Tracking Form, gives Generator signed copy, and retains all other copies.

Transporter may consolidate loads and initiate a new Tracking Form.*

Destination (final disposal) facility accepts waste, signs Tracking Form, gives one copy to the Transporter, keeps copy for its own records, and returns a completed copy to the initiator (party that fills in Generator block) of the Form.

*Initiators of Tracking Forms become Generators in effect under this Tracking System.

The **Waste Management** System

There are special requirements for generators, transporters, and facilities to help ensure that regulated wastes are handled safely and received by the appropriate destination facility.

Generators

A person or institution located in a participating state, generating 50 pounds or more of regulated medical waste monthly and shipping it off site, is fully covered by the demonstration program. These generators must separate, package, label, mark, and track medical wastes according to the regulation.

Generators producing and shipping less than 50 pounds a month must also prepare their wastes properly for shipment. They may use a log to account for wastes, however, instead of a tracking form.

On the other hand, generators that dispose of waste on site or in the sewer system are not covered by the requirements of this program. Generators that treat and destroy waste on site, such as by incineration, are subject to certain reporting and recordkeeping requirements. Wastes that are treated and destroyed or disposed of on site or into sewers are not counted toward the 50 pound monthly limit. All medical wastes—even those treated, destroyed, and disposed on site—must be stored properly.

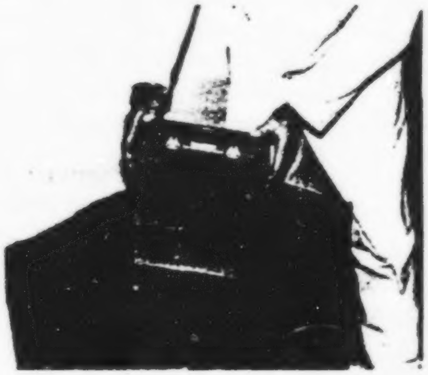
Transporters

Transporters must notify EPA of their intention to comply with the program to be allowed to accept regulated medical wastes for transport. EPA maintains a list of transporters who have notified EPA of their intent to transport regulated medical wastes generated in each participating state. This list is available to generators. Transporters must follow rules governing their vehicles and addressing tracking, recordkeeping, and reporting of waste shipments. They must also make sure that wastes they pick up have been properly prepared for shipping and that the tracking form is accurate.

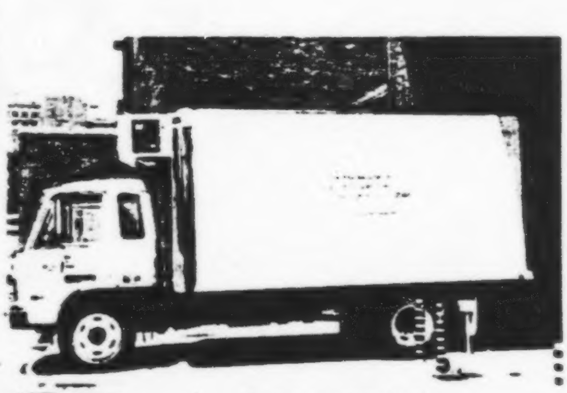
Treatment, Destruction, and Disposal Facilities

The demonstration tracking program rules apply to owners and operators of treatment, destruction, and disposal facilities receiving regulated medical wastes. These facilities include incinerators, landfills, and treatment operations that grind, steam sterilize, or treat wastes with disinfectants, heat, or radiation.

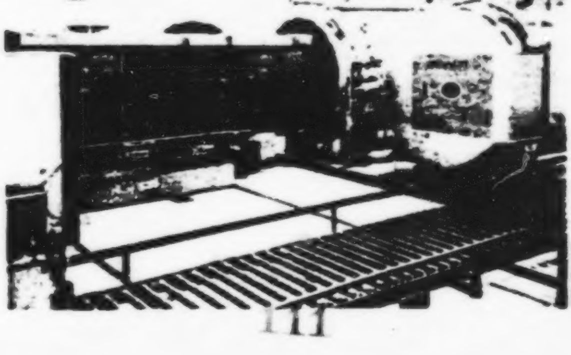
Like generators and transporters, treatment, destruction, and disposal facilities must keep track of medical wastes and maintain records. Facilities must send a signed copy of the tracking form back to the generator or initiator of the tracking form when the wastes have been accepted for disposal. The facility owners or operators must investigate any discrepancies between the accompanying papers and the shipments they receive; if, after investigation, there is still a discrepancy, they must report it to EPA and the generator state agency.



Generator packaging medical waste



Transporter vehicle



Steam sterilizing, or autoclaving, before disposal

Reproduced from best available copy.

Section 2: A Detailed Guide for Regulated Medical Waste Treatment, Destruction, and Disposal Facilities

This section includes instructions for facilities that treat, destroy, or dispose of regulated medical wastes to help them comply with federal regulations. It outlines separate requirements for "destination" facilities and "intermediate handlers." Checklists are included.

This program does not address the actual treatment, destruction, or disposal processes for the waste; these processes may be covered by state or local laws and regulations.

Profile of a Destination Facility, or Final Disposer

Destination facilities treat and destroy or dispose of regulated medical wastes. These facilities include landfills, incinerators, and operations that treat and destroy wastes using techniques such as steam sterilizing combined with grinding. Facilities that treat and destroy or landfill regulated medical wastes are end points for the tracking system. Moreover, a facility that accepts treated waste by a process such as steam sterilization and then destroys it by grinding or shredding is also a destination facility, thus an end point for tracking. Under this program, tracking is not required after the waste has been both treated and destroyed or received at a landfill or incinerator.

Profile of an Intermediate Handler

Facilities that treat but do not destroy medical wastes or destroy but do not treat them are not end points for regulated medical wastes. They are referred to as intermediate handlers. Intermediate handlers include facilities that just shred or grind untreated wastes or that just steam sterilize medical wastes that are not yet destroyed.

Facilities Subject to All Requirements

Fully covered by the tracking program are facilities—final destination and intermediate handlers—accepting regulated medical waste generated in a participating state and required to be accompanied by a tracking form. (Each shipment of 50 pounds or more must have a tracking form.) Facilities located in nonparticipating states accepting waste from a participating state are also regulated under the program. As explained in the following pages, covered facilities must inspect packages, noting any discrepancies between the tracking form and the shipment received; sign and return tracking forms; file discrepancy reports, as necessary; and keep records.

Exceptions to the Full Tracking Program

Generally, transporters consolidate smaller shipments and prepare tracking forms to accompany them. However, in some cases facilities may accept shipments of less than 50 pounds not accompanied by a tracking form from small generators producing 50 pounds or less in a month. These shipments may be recorded in a log if

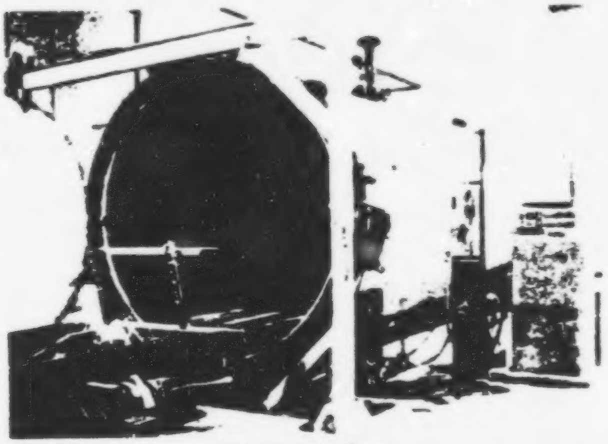
- the facility has a written agreement with the generator to accept the waste and
- the generator transports the waste in the generator's or an employee's vehicle.

For each small shipment accepted, the facility must keep records, such as a log, that include the

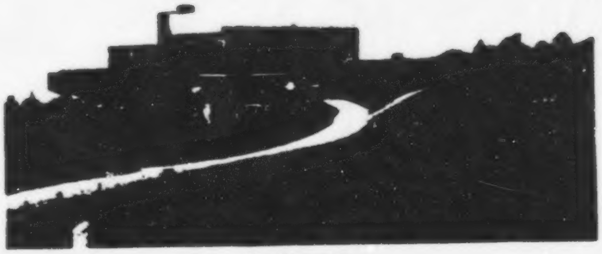
- date the waste was accepted.
- name and state permit or identification number of the generator that initiated the shipment, or the generator's address if the state does not issue numbers.
- total weight of the waste.
- signature of the person accepting the waste.

Facilities may also accept sharps sent through the U.S. Postal Service registered mail, return receipt requested.

Facilities incinerating regulated medical waste generated on site are not required to track wastes under this program. There are special requirements for on-site incinerators, however. These can be found in 40 CFR Part 259, Subpart G.



Steam autoclave



Incinerator

Landfill

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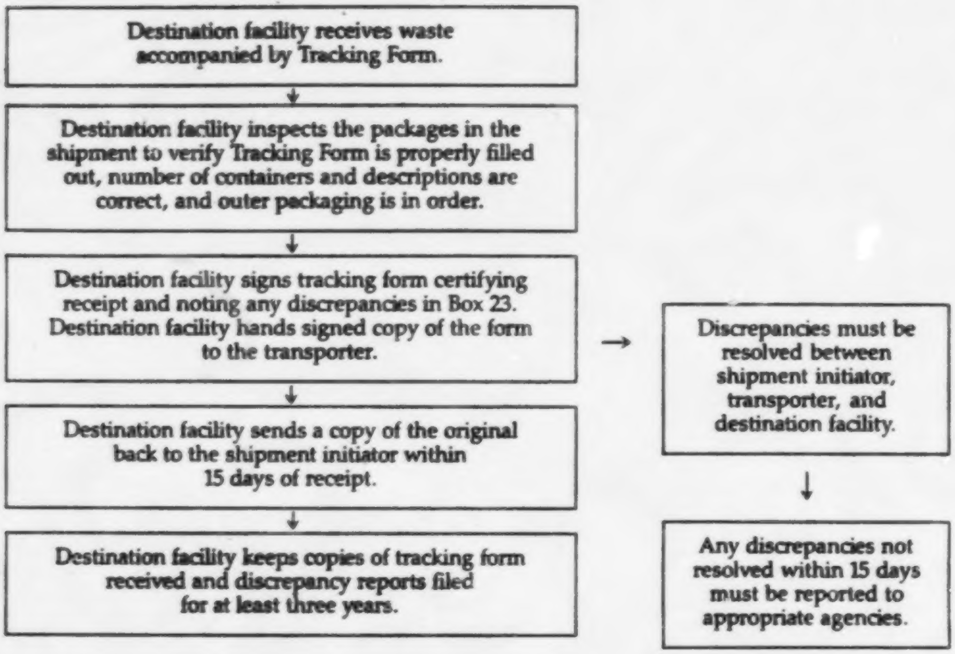
Tracking Medical Wastes

The tracking form ensures that each shipment of waste reaches its destination. Therefore, it is crucial for a destination facility or an intermediate handler receiving a shipment of waste to sign a copy of this form, give a copy to the transporter upon accepting the waste, and follow the correct procedure for returning a copy to the generator or initiator of the tracking form. Figure 3 shows the medical waste tracking process for destination facilities; Figure 4, for intermediate handlers. Facilities receiving wastes by rail should refer to Figure 5.

FIGURE 3. Tracking Process for Destination Facility.



Destination facility receives waste accompanied by Tracking Form.

Destination facility inspects the packages in the shipment to verify Tracking Form is properly filled out, number of containers and descriptions are correct, and outer packaging is in order.

Destination facility signs tracking form certifying receipt and noting any discrepancies in Box 23. Destination facility hands signed copy of the form to the transporter.

Destination facility sends a copy of the original back to the shipment initiator within 15 days of receipt.

Destination facility keeps copies of tracking form received and discrepancy reports filed for at least three years.

Discrepancies must be resolved between shipment initiator, transporter, and destination facility.

Any discrepancies not resolved within 15 days must be reported to appropriate agencies.

Intermediate Handler Special Rules

When an intermediate handler accepts regulated medical waste with a tracking form, the handler must first check the shipment, note any discrepancies, sign, and give a signed copy of the form to the transporter. Since the intermediate handler does not both treat and destroy or dispose of waste, the handler is required to continue tracking the waste to a destination facility for final disposal.

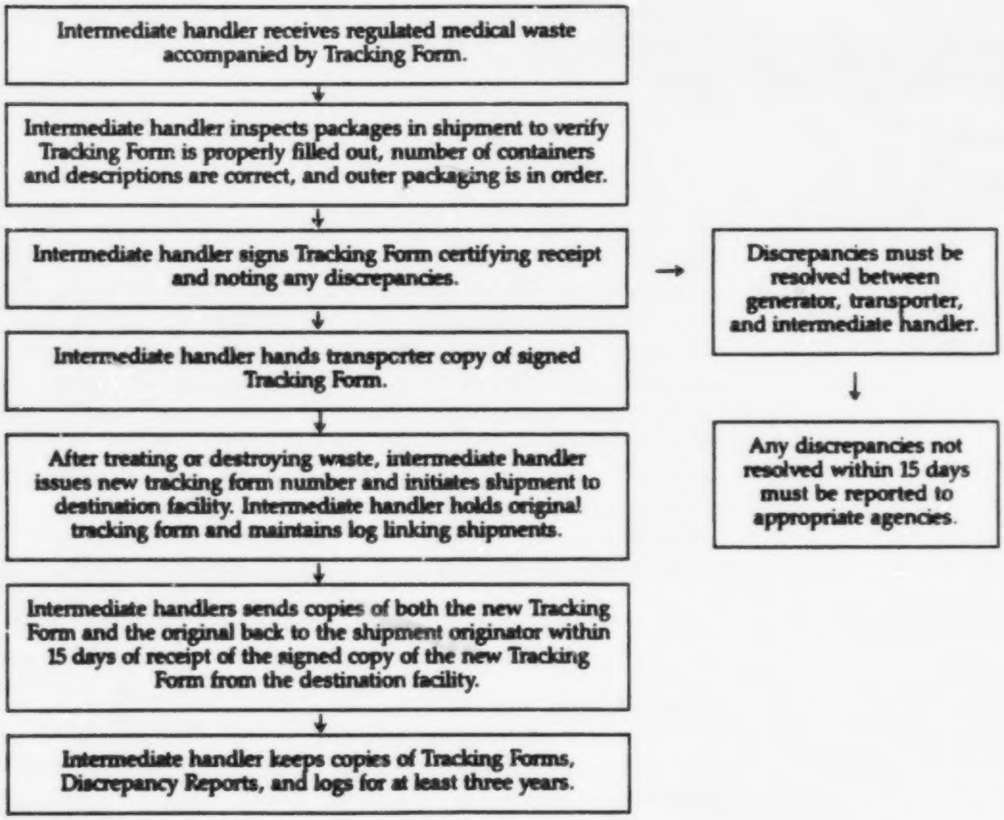
After treating or destroying the waste, the intermediate handler must initiate a new tracking form to indicate any changes in the number, weight, or contents of the processed waste, and the handler must enter a new tracking form number in Box 21 of the original form (see Figure 1) as a link between the new waste shipment and the one received for processing. In addition, the handler must assume the role of a generator, meeting all the pre-transporting and generator rules (refer to *Managing and Tracking Medical Wastes: A Guide to the Federal Program for Generators*).

Furthermore, the intermediate handler must maintain a log that further links the information on the new tracking form with that on the original tracking form. The log must include the

- name of generator.
- generator's state permit or identification number, or address if the state does not issue a permit or identification number.
- date of the original shipment or generator's tracking form number.
- new tracking form number.

When the intermediate handler receives the signed and returned new tracking form from the destination facility acknowledging receipt of the waste for disposal, the handler attaches this new form to a copy of the original form and sends both to the original generator. These forms are to be sent within 15 days to assure the original generator that the waste was received at the destination facility and that no exception reporting is needed. (The generator is required to file an exception report if the original form is not returned within 45 days.)

FIGURE 4. Tracking Process for Intermediate Handler.



Intermediate handler receives regulated medical waste accompanied by Tracking Form.

Intermediate handler inspects packages in shipment to verify Tracking Form is properly filled out, number of containers and descriptions are correct, and outer packaging is in order.

Intermediate handler signs Tracking Form certifying receipt and noting any discrepancies.

Discrepancies must be resolved between generator, transporter, and intermediate handler.

Any discrepancies not resolved within 15 days must be reported to appropriate agencies.

Intermediate handler hands transporter copy of signed Tracking Form.

After treating or destroying waste, intermediate handler issues new tracking form number and initiates shipment to destination facility. Intermediate handler holds original tracking form and maintains log linking shipments.

Intermediate handlers sends copies of both the new Tracking Form and the original back to the shipment originator within 15 days of receipt of the signed copy of the new Tracking Form from the destination facility.

Intermediate handler keeps copies of Tracking Forms, Discrepancy Reports, and logs for at least three years.

Figure 5. Receiving Medical Wastes by Rail

A destination facility or an intermediate handler may accept medical wastes shipped by rail. These wastes are to be accompanied by a tracking form or, in some cases, by shipping papers containing all information required on the tracking form, except signatures. If no tracking form comes with the waste, the facility owner or operator should expect to receive it by mail or other means from the last non-rail transporter. In any case, the owner or operator upon receipt of the rail shipment

- checks the shipment and notes discrepancies, if any.
- signs and dates each copy of the tracking form or, if no tracking form has been received, shipping papers.
- gives a copy of the signed tracking form, or shipping papers, immediately to the rail transporter.
- sends (if a destination facility) a copy of the signed and dated form within 15 days to the generator or the initiator of the tracking form. If the tracking form has not been received within 15 days, the destination facility sends a signed and dated copy of the shipping papers to the shipment initiator.
- holds (if an intermediate handler) a copy of the tracking form or shipping papers. When the handler receives a signed new tracking form from the destination facility indicating that the waste was received, the handler sends copies of both the new and original tracking forms to the generator or initiator of the original form (or shipping papers).

Tracking Form Discrepancies

In some cases, a tracking form may indicate differences between what is received and what is noted on the form or shipping papers. For example, the actual number of containers or the categories of waste may not be consistent with the information on the form, the packaging may be leaking, or the tracking form may be missing or incomplete. If such significant discrepancies occur, the owner or operator of a destination facility or an intermediate handler must try to resolve the problem. If the discrepancy cannot be resolved, it must be reported in writing within 15 days to the EPA Regional Administrator for both the generator and the facility states, and to the generator state agency. The letter is to describe the problem and any attempts to solve it; a legible copy of the tracking form or shipping papers is to be attached. If a tracking form is required to accompany the waste but is missing or incomplete, the report is to specify the quantity of waste received and identify the generator and transporter.

Keeping Records

Facility owners or operators receiving regulated medical waste are to maintain records for three years after accepting the waste. The following information must be on file:

- copies of all tracking and shipping forms and logs.
- name and state identification or permit number of each generator that delivered waste directly to the facility, or the generator's address if the state does not issue numbers; the total weight accepted; and the date the waste was accepted.
- copies of all discrepancy reports.

Other Reports

Owners and operators may be required to provide reports to EPA concerning how much medical waste was received and what treatment and disposal methods were applied.

Medical Waste Facility Checklist

If you represent a facility receiving medical waste regulated under this program, the following list is designed to help you comply with the program requirements.

_______ Facility (owner or operator) is located in a participating or nonparticipating state and receives regulated medical waste generated in a participating state. (If yes, continue.)

_______ Facility accepts shipment of 50 pounds or less of sharps through U.S. Postal Service. (If yes, sign mail receipt.)

_______ Facility accepts shipments of 50 pounds or less from generator that has a contract and delivers waste in generator vehicle. (If yes, maintain facility log for three years.)

_______ Facility accepts regulated medical waste accompanied by a tracking form or shipping papers. (If yes, continue.)

_______ Facility owner or operator examines tracking form to see that it is filled out and signed by both the generator (Box 15) and transporter (Box 16), and if applicable, the intermediate handler (Box 20). (Continue.)

_______ Facility owner or operator examines the shipment and notes any discrepancies (Box 23) between the tracking form and the shipment, such as piece count. (Continue.)

_______ Facility owner or operator signs tracking form or shipping papers.

_______ Facility owner/operator hands copy to transporter.

_______ Discrepancies are investigated and, if not resolved within 15 days, letter sent to EPA Regional Administrator(s) for generator and facility state(s), and generator state agencies.

If Facility is a Destination Facility

_______ Destination facility sends copy of tracking form or shipping papers back to tracking form initiator.

_______ Copies of tracking forms, receipts, shipping papers, logs, and discrepancy reports are retained in facility records for three years.

Or If Facility is an Intermediate Handler

_______ Intermediate handler issues a new tracking form number in Box 21, initiates a new tracking form to accompany waste to destination facility, and maintains log.

_______ Intermediate handler, within 15 days of receipt of signed and returned form from destination facility, attaches original form to new tracking form and sends both copies to generator or initiator of original form.

_______ Copies of tracking forms, receipts, shipping papers, logs, and discrepancy reports are retained in facility records for three years.

Glossary

Following are the classes of regulated medical wastes and a description of each.

Cultures and Stocks	Cultures and stocks of infectious agents and associated biologicals including: cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.
Pathological Wastes	Human pathological wastes, including tissues, organs, and body parts and body fluids that are removed during surgery or autopsy or other medical procedures, and specimens of body fluids and their containers.
Human Blood and Blood Products	Liquid waste human blood; products of blood; items saturated and/or dripping with human blood; or items that were saturated and/or dripping with human blood that are now caked with dried human blood including serum, plasma, and other blood components, and their containers, which were used or intended for use in either patient care, testing and laboratory analysis, or the development of pharmaceuticals. Intravenous bags are also included in this category.
Sharps	Sharps that have been used in animal or human patient care or treatment or in medical, research, or industrial laboratories. These include hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.
Animal Waste	Contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals, or testing of pharmaceuticals.
Isolation Wastes	Biological waste and discarded materials contaminated with blood, excretion, exudates, or secretions from humans who are isolated to protect others from certain highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.
Unused Sharps	The following unused, discarded sharps: hypodermic needles, suture needles, syringes, and scalpel blades.

The following terms are defined here to address the management of medical wastes. They may be different from those federal definitions used for solid or hazardous waste.

Biologicals	Preparations made from living organisms and their products, including vaccines, cultures, etc. intended for use in diagnosing, immunizing, or treating humans or animals, or in related research.
Blood Products	Any product derived from human blood, including but not limited to blood plasma, platelets, red or white blood corpuscles, and other derived licensed products, such as interferon.
Body Fluids	Liquid emanating or derived from humans and limited to blood; cerebrospinal, synovial, pleural, peritoneal, and pericardial fluids; and semen and vaginal secretions.
Central Collection Point	A location where a generator consolidates regulated medical waste brought together from original generation points prior to its transport off-site or its treatment on-site.
Container	Any portable device in which a material is stored, transported, disposed of, or otherwise handled. The term container, when describing the packaging requirements, does not include items that are regulated medical waste.
Decontamination	The process of reducing or eliminating the presence of harmful substances, such as infectious agents, so as to reduce the likelihood of disease transmission from those substances.
Destination Facility	The disposal facility, the incineration facility, or the facility that both treats and destroys regulated medical waste to which medical wastes are shipped.
Destroyed Regulated Medical Waste	Regulated medical waste that has been ruined, torn apart, or mutilated through processes such as thermal treatment, melting, shredding, grinding, tearing, or breaking, so that it is no longer generally recognizable as medical waste, but has not yet been treated. It does not mean compacted regulated medical waste.

estruction Facility	A facility that destroys regulated medical waste by ruining or mutilating it, or tearing it apart.
acility	All contiguous land and structures, other appurtenances, and improvements on the land used for treating, destroying, storing, or disposing of regulated medical waste. A facility may consist of several treatment, destruction, storage, or disposal operational units.
enerator	Any person, by site, whose act or process produces regulated medical waste or whose act first causes a regulated medical waste to become subject to regulation. In the case where more than one person (e.g., doctors with separate medical practices) is located in the same building, each individual business entity is a separate generator. [Note: see definition of "person."]
nfectious Agent	Any organism (such as a virus or a bacteria) that is capable of being communicated by invasion and multiplication in body tissues and capable of causing disease or adverse health impacts in humans.
ntermediate Handler	A facility that either treats regulated medical waste or destroys regulated medical waste but does not do both. The term does not include transporters.
aboratory	Any research, analytical, or clinical facility that performs health care-related analysis or service. This includes medical, pathological, pharmaceutical, and other research, commercial, or industrial laboratories.
andfill	A disposal facility or part of a facility where regulated medical waste is placed in or on the land and which is not a land treatment facility, a surface impoundment, or an injection well.
edical Waste	Any solid waste which is generated in the diagnosis, treatment (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. The term does not include any hazardous waste identified or listed under 40 CFR Part 261 or any household waste as defined in 40 CFR §261.4(b)(1).
n-site	The same or geographically contiguous property which may be divided by public or private right of way, provided the entrance and exit between the properties is at a crossroads intersection, and access is by crossing as opposed to going along the right of way. Non-contiguous properties owned by the same person but connected by a right of way which he controls and to which the public does not have access is also considered on-site property.
Original Generation Point	Location where regulated medical waste first becomes waste (is "generated").
Oversized Regulated Medical Waste	Medical waste that is too large to be placed in plastic bags or standard containers.
Package or Outside Package	The packaging/container and its contents.
Packaging	The assembly of one or more containers and any other components necessary to assure minimum compliance with the program's packaging requirements.
Person	An individual, trust, firm, joint stock company, corporation (including a government corporation), partnership, association, state, municipality, commission, political subdivision of a state, any interstate body, or any department, agency or instrumentality of the United States.
Storage	The temporary holding of regulated medical wastes at a designated accumulation area before treatment, disposal, or transport to another location.
Transfer Facility	Any transportation-related facility including loading docks, parking areas, storage areas and other similar areas where shipments of regulated medical waste are held during the course of transportation. Also, a location in which medical waste is transferred between two vehicles.
Treated Regulated Medical Waste	Regulated medical waste that has been treated to substantially reduce or eliminate its potential for causing disease, but that has not yet been destroyed.
Treatment	When used to refer to waste handling, it means any method, technique, or process designed to change the biological character or composition of any regulated medical waste so as to substantially reduce or eliminate its potential for causing disease.

Appendix

EPA Regional Offices

Region I
State Waste Programs Branch
JFK Federal Building
Boston, MA 02203
(617) 573-5758

Region II
Air and Waste Management Division
26 Federal Plaza
New York, NY 10278
(212) 264-5166

Caribbean Field Office
(809) 729-6920

Region III
Waste Management Branch
841 Chestnut Building
Philadelphia, PA 19107
(215) 597-2842

Region IV
Hazardous Waste Management Division
345 Courtland Street, N.E.
Atlanta, GA 30365
(404) 347-3016

Region V
RCRA Activities
230 S. Dearborn Street
Chicago, IL 60604
(312) 353-9510

Region VI
Air and Hazardous Materials Division
1445 Ross Avenue
Suite 1200
Dallas, TX 75270
(214) 655-6652

Region VII
RCRA Branch
726 Minnesota Avenue
Kansas City, KS 66101
(913) 236-2856

Region VIII
Waste Management Division
999 18th Street, Suite 500
Denver, CO 80202
(303) 293-1496

Region IX
Toxics and Waste Management
215 Fremont Street
San Francisco, CA 94105
(415) 974-8388

Region X
Waste Management Branch
1200 Sixth Avenue
Seattle, WA 98101
(206) 442-6501

United States
Environmental Protection
Agency

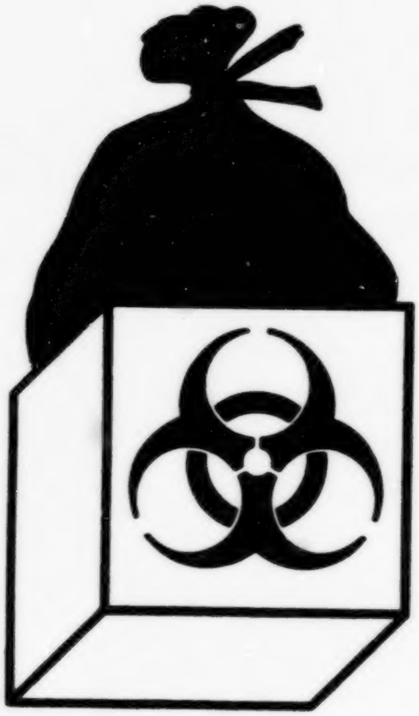
Solid Waste and
Emergency Response
(OS-305)

EPA/530-SW-89-023
September 1989

EPA

Managing and Tracking Medical Wastes

A Guide to the Federal Program for Treatment, Destruction, and Disposal Facilities



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Introduction

In response to the growing public concern over mismanagement of medical wastes, Congress enacted the *Medical Waste Tracking Act*.

The Act charges the Environmental Protection Agency with responsibility for implementing a two-year demonstration medical waste tracking program that will help determine the best medical waste management procedures for the future. The program's goal is to find an effective means to ensure that regulated medical wastes get from their point of generation to their point of disposal.

Generators of regulated medical wastes will be part of the new demonstration tracking program in the States of Connecticut, New Jersey, New York, and Rhode Island, and the Commonwealth of Puerto Rico. Transporters and facilities that store, treat, destroy, and dispose of these wastes will also be part of the program.

This guide offers general information about the tracking program (Section 1) and specific instructions for facilities that treat, destroy, or dispose of regulated medical waste (Section 2). Section 2 includes requirements for facilities that dispose of these wastes—destination facilities—and slightly different requirements for facilities that treat *or* destroy wastes—intermediate handlers. Separate guides in this series are provided for generators and transporters of regulated medical wastes.

This guide describes the federal program only. It is designed to help facilities that treat, destroy, or dispose of wastes generated in participating states comply with the program. For more complete information, facility owners and operators should refer to "Standards for the Tracking and Management of Medical Waste," interim final rule (40 CFR Part 259). In addition, states participating in the program have their own rules for managing medical waste. For further assistance, addresses and phone numbers of EPA Regional Offices are listed in Appendix A.

For additional copies of *Managing and Tracking Medical Wastes* or a copy of 40 CFR Part 259, call the RCRA Hotline at (800) 424-9346 or, in Washington, D.C., 382-3000.

The cooperation of all participants in the management of regulated medical waste will assure the success of this important demonstration program and reduce public exposure to the waste.

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Section 1: The Medical Waste Tracking Program

In response to public concern over the mismanagement of medical wastes, the *Medical Waste Tracking Act* was enacted in the fall of 1988. The law directs the Environmental Protection Agency (EPA) to establish a two-year demonstration program for tracking medical wastes.

Under this law, EPA has issued regulations entitled "Standards for the Tracking and Management of Medical Waste" (40 CFR Part 259). The regulations list the medical wastes to be tracked and cover standards for separating, packaging, and labeling medical wastes before sending them for treatment or disposal. The results of the demonstration program are intended to help determine whether such a program should be extended nationwide.

> **The *Medical Waste Tracking Act* amends the *Resource Conservation and Recovery Act* (RCRA) by adding Subtitle J. It defines medical waste as ". . . any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. . . ."**

Participating in the demonstration program are the States of Connecticut, New Jersey, New York, and Rhode Island, and the Commonwealth of Puerto Rico. The regulation is an interim final rule. It will be in effect for two years, until June 22, 1991. In Connecticut, New Jersey, and New York, the program is effective beginning June 22, 1989; in Rhode Island and the Commonwealth of Puerto Rico, the program is effective beginning July 24, 1989.

The demonstration program involves **only** regulated medical wastes **generated in one of the states** participating in the program, even when these wastes leave the state. The program sets up a system for tracking the waste from the generator to the disposal site. A tracking form that accompanies this waste is signed and a copy is retained by a representative of the waste generator and each transporter, transfer station, and treatment, destruction, and disposal facility handling it. When the final disposer—the destination facility—accepts the waste, a copy of the signed tracking form is returned to the generator. In this way the generator is assured that the waste was received for disposal. The tracking system includes "exception" and "discrepancy" reporting to alert EPA and the states if wastes are not being handled properly.

To minimize contact with regulated medical wastes by workers, handlers, and the public, the program includes specific requirements for segregating, packaging, labeling, marking, and storing medical wastes before they are shipped to another site for treatment, destruction, or disposal. Other requirements include recordkeeping, reporting, and enforcement. EPA will evaluate the success of the program and report the results to Congress.

Waste Managers Participation

This booklet is intended to help facilities that treat, destroy, or dispose of regulated medical wastes generated in the participating states comply with the federal rules. Facilities in these states must also follow rules required by the individual states. Owners and operators of facilities should check with their state officials for clarification of state rules. While participating states use the same basic tracking form as EPA's, some states might regulate more wastes or require special permits or licenses. Participating states are authorized to enforce this program.

The demonstration program includes medical waste generators in participating states; transporters of those wastes; and owners and operators of treatment, destruction, and disposal facilities that manage waste generated in participating states, even if their facilities are located in nonparticipating states. Similarly, the program includes transporters carrying regulated medical wastes from participating states, even if the wastes are then taken to nonparticipating states. The program includes vessels and transporters that take medical wastes to shore from ships docked in participating states. Federal facilities generating regulated medical wastes in participating states are also covered under this program.

Regulated Medical Wastes

Medical wastes affected by the pilot program include

- cultures and stocks of infectious agents.
- human blood and blood products.
- human pathological wastes, including those from surgery and autopsy.
- contaminated animal carcasses from medical research.
- wastes from patients isolated with highly communicable diseases.
- all used sharp implements, such as needles and scalpels, and certain unused sharps.

These regulated medical wastes fall into two categories: untreated or treated. The Glossary provides detailed descriptions of these medical wastes.

The demonstration program focuses on wastes that historically have been improperly managed and are most likely to pose a substantial threat to human health and the environment. However, any additional waste that a health care professional believes may pose a risk should be handled as a regulated medical waste.

Mixtures of regulated medical waste and general trash are regulated as medical waste. Mixtures of regulated medical waste and hazardous waste are usually regulated as hazardous waste. However, if medical waste is mixed with hazardous waste, which falls under the small quantity hazardous waste exemption, then the waste mixture must be tracked as medical waste under this program.

Pre-transporting Procedures

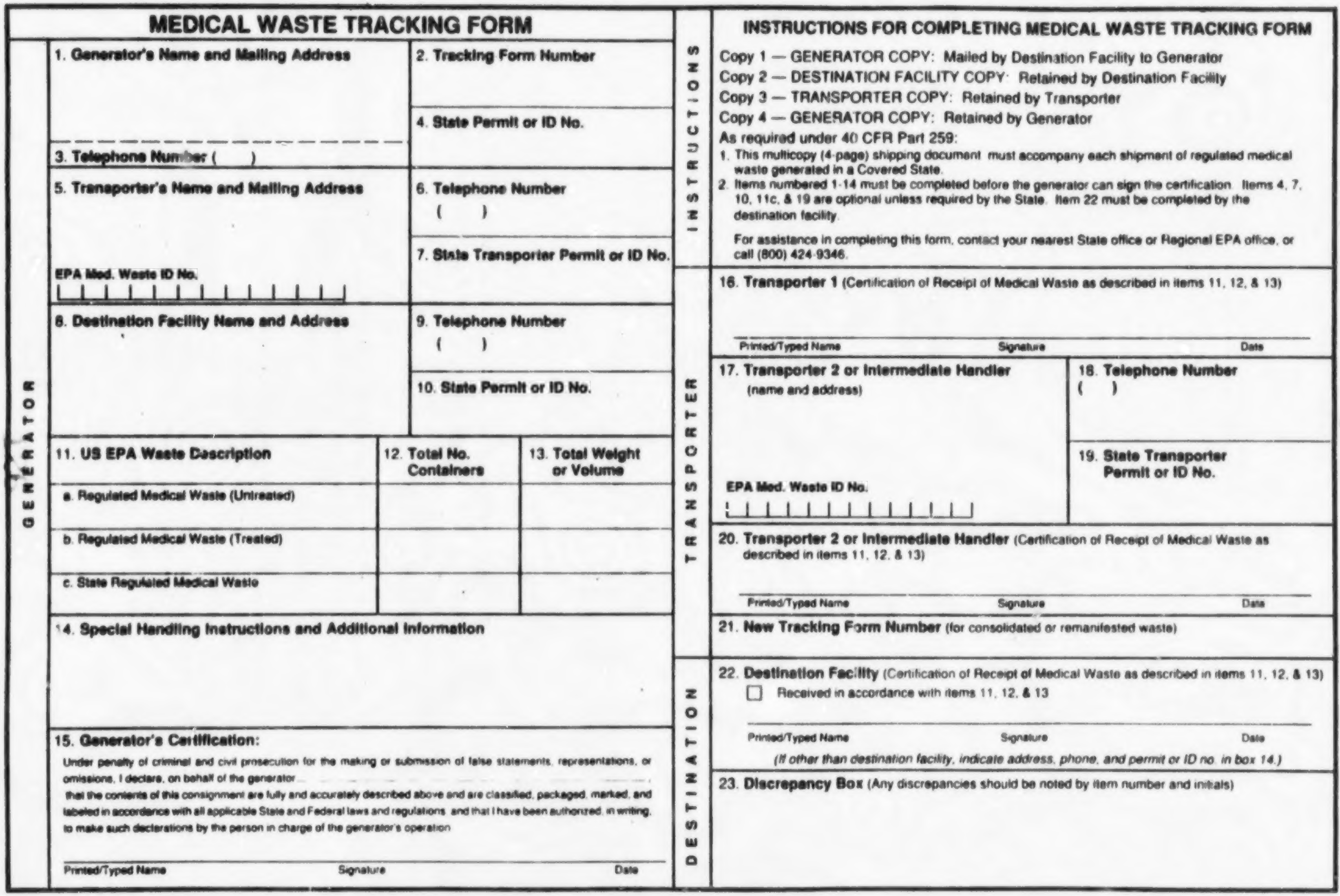
Regulated medical wastes that are to be transported to an off-site facility for treatment or disposal must be properly prepared for shipping. First, the wastes must be separated from general trash, and then sharp items, fluids, and other medical wastes must be separated from each other. They are then packaged to prevent tearing, breaking, or leaking during shipping and handling.

Packages are to be labeled and marked to identify the contents of the package and generator and transporter of the waste. In addition, stored wastes must be maintained to prevent them from coming into contact with workers or the public.

Tracking Regulated Medical Wastes

At the core of the medical waste demonstration tracking system is a MEDICAL WASTE TRACKING FORM (see Figure 1). This form must accompany each off-site shipment that weighs 50 pounds or more. Shipments from generators of less than 50 pounds a month may be combined onto one tracking form by the transporter. Generators, transporters, and treatment, destruction, and disposal facilities are responsible for filling in, forwarding, and retaining a copy of this form for their records. Figure 2 illustrates how the medical waste tracking system works.

FIGURE 1. Medical waste tracking form.



MEDICAL WASTE TRACKING FORM

GENERATOR

1. Generator's Name and Mailing Address

2. Tracking Form Number

3. Telephone Number (   )

4. State Permit or ID No.

5. Transporter's Name and Mailing Address

6. Telephone Number (   )

7. State Transporter Permit or ID No.

EPA Med. Waste ID No.

8. Destination Facility Name and Address

9. Telephone Number (   )

10. State Permit or ID No.

11. US EPA Waste Description	**12. Total No. Containers**	**13. Total Weight or Volume**
a. Regulated Medical Waste (Untreated)		
b. Regulated Medical Waste (Treated)		
c. State Regulated Medical Waste		

14. Special Handling Instructions and Additional Information

15. Generator's Certification:

Under penalty of criminal and civil prosecution for the making or submission of false statements, representations, or omissions, I declare, on behalf of the generator ______ that the contents of this consignment are fully and accurately described above and are classified, packaged, marked, and labeled in accordance with all applicable State and Federal laws and regulations, and that I have been authorized, in writing, to make such declarations by the person in charge of the generator's operation.

Printed/Typed Name Signature Date

INSTRUCTIONS

INSTRUCTIONS FOR COMPLETING MEDICAL WASTE TRACKING FORM

Copy 1 — GENERATOR COPY: Mailed by Destination Facility to Generator
Copy 2 — DESTINATION FACILITY COPY: Retained by Destination Facility
Copy 3 — TRANSPORTER COPY: Retained by Transporter
Copy 4 — GENERATOR COPY: Retained by Generator

As required under 40 CFR Part 259:

1. This multicopy (4-page) shipping document must accompany each shipment of regulated medical waste generated in a Covered State.
2. Items numbered 1-14 must be completed before the generator can sign the certification. Items 4, 7, 10, 11c, & 19 are optional unless required by the State. Item 22 must be completed by the destination facility.

For assistance in completing this form, contact your nearest State office or Regional EPA office, or call (800) 424-9346.

TRANSPORTER

16. Transporter 1 (Certification of Receipt of Medical Waste as described in items 11, 12, & 13)

Printed/Typed Name Signature Date

17. Transporter 2 or Intermediate Handler (name and address)

EPA Med. Waste ID No.

18. Telephone Number (   )

19. State Transporter Permit or ID No.

20. Transporter 2 or Intermediate Handler (Certification of Receipt of Medical Waste as described in items 11, 12, & 13)

Printed/Typed Name Signature Date

21. New Tracking Form Number (for consolidated or remanifested waste)

DESTINATION

22. Destination Facility (Certification of Receipt of Medical Waste as described in items 11, 12, & 13)

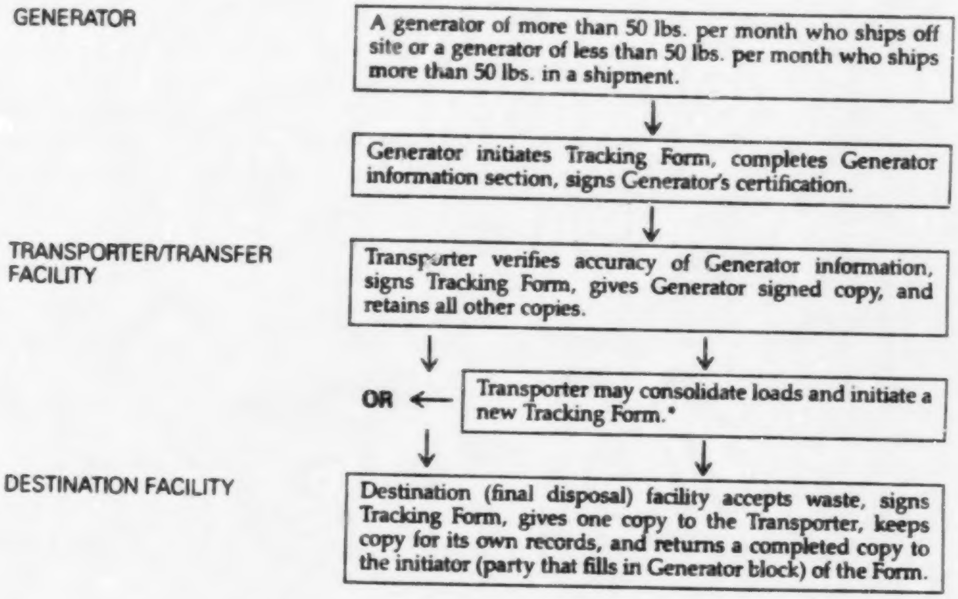
☐ Received in accordance with items 11, 12, & 13

Printed/Typed Name Signature Date

(If other than destination facility, indicate address, phone, and permit or ID no. in box 14.)

23. Discrepancy Box (Any discrepancies should be noted by item number and initials)

FIGURE 2. Medical waste tracking system. All medical waste shipments required to be accompanied by a tracking form are tracked from generator to final disposal, or destination facility.



GENERATOR

A generator of more than 50 lbs. per month who ships off site or a generator of less than 50 lbs. per month who ships more than 50 lbs. in a shipment.

Generator initiates Tracking Form, completes Generator information section, signs Generator's certification.

TRANSPORTER/TRANSFER FACILITY

Transporter verifies accuracy of Generator information, signs Tracking Form, gives Generator signed copy, and retains all other copies.

OR

Transporter may consolidate loads and initiate a new Tracking Form.*

DESTINATION FACILITY

Destination (final disposal) facility accepts waste, signs Tracking Form, gives one copy to the Transporter, keeps copy for its own records, and returns a completed copy to the initiator (party that fills in Generator block) of the Form.

*Initiators of Tracking Forms become Generators in effect under this Tracking System.

The Waste Management System

There are special requirements for generators, transporters, and facilities to help ensure that regulated wastes are handled safely and received by the appropriate destination facility.

Generators

A person or institution located in a participating state, generating 50 pounds or more of regulated medical waste monthly and shipping it off site, is fully covered by the demonstration program. These generators must separate, package, label, mark, and track medical wastes according to the regulation.

Generators producing and shipping less than 50 pounds a month must also prepare their wastes properly for shipment. They may use a log to account for wastes, however, instead of a tracking form.

On the other hand, generators that dispose of waste on site or in the sewer system are not covered by the requirements of this program. Generators that treat and destroy waste on site, such as by incineration, are subject to certain reporting and recordkeeping requirements. Wastes that are treated and destroyed or disposed of on site or into sewers are not counted toward the 50 pound monthly limit. All medical wastes—even those treated, destroyed, and disposed on site—must be stored properly.

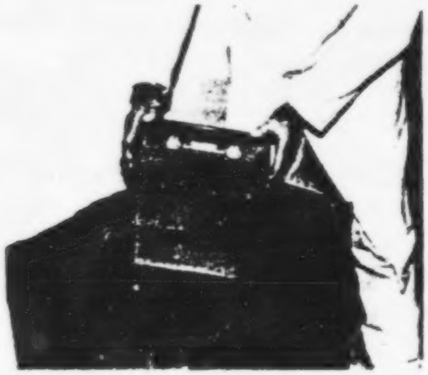
Transporters

Transporters must notify EPA of their intention to comply with the program to be allowed to accept regulated medical wastes for transport. EPA maintains a list of transporters who have notified EPA of their intent to transport regulated medical wastes generated in each participating state. This list is available to generators. Transporters must follow rules governing their vehicles and addressing tracking, recordkeeping, and reporting of waste shipments. They must also make sure that wastes they pick up have been properly prepared for shipping and that the tracking form is accurate.

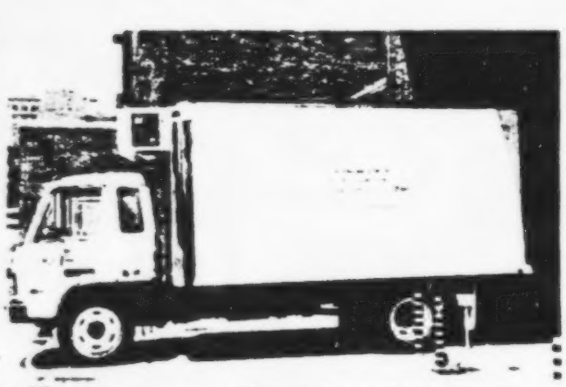
Treatment, Destruction, and Disposal Facilities

The demonstration tracking program rules apply to owners and operators of treatment, destruction, and disposal facilities receiving regulated medical wastes. These facilities include incinerators, landfills, and treatment operations that grind, steam sterilize, or treat wastes with disinfectants, heat, or radiation.

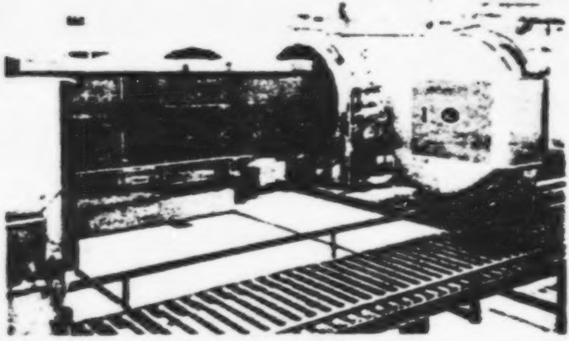
Like generators and transporters, treatment, destruction, and disposal facilities must keep track of medical wastes and maintain records. Facilities must send a signed copy of the tracking form back to the generator or initiator of the tracking form when the wastes have been accepted for disposal. The facility owners or operators must investigate any discrepancies between the accompanying papers and the shipments they receive; if, after investigation, there is still a discrepancy, they must report it to EPA and the generator state agency.



Generator packaging medical waste



Transporter vehicle



Steam sterilizing, or autoclaving, before disposal

Section 2:

A Detailed Guide for Regulated Medical Waste Treatment, Destruction, and Disposal Facilities

This section includes instructions for facilities that treat, destroy, or dispose of regulated medical wastes to help them comply with federal regulations. It outlines separate requirements for "destination" facilities and "intermediate handlers." Checklists are included.

This program does not address the actual treatment, destruction, or disposal processes for the waste; these processes may be covered by state or local laws and regulations.

Profile of a Destination Facility, or Final Disposer

Destination facilities treat and destroy or dispose of regulated medical wastes. These facilities include landfills, incinerators, and operations that treat and destroy wastes using techniques such as steam sterilizing combined with grinding. Facilities that treat and destroy or landfill regulated medical wastes are end points for the tracking system. Moreover, a facility that accepts treated waste by a process such as steam sterilization and then destroys it by grinding or shredding is also a destination facility, thus an end point for tracking. Under this program, tracking is not required after the waste has been both treated and destroyed or received at a landfill or incinerator.

Profile of an Intermediate Handler

Facilities that treat but do not destroy medical wastes or destroy but do not treat them are not end points for regulated medical wastes. They are referred to as intermediate handlers. Intermediate handlers include facilities that just shred or grind untreated wastes or that just steam sterilize medical wastes that are not yet destroyed.

Facilities Subject to All Requirements

Fully covered by the tracking program are facilities—final destination and intermediate handlers—accepting regulated medical waste generated in a participating state and required to be accompanied by a tracking form. (Each shipment of 50 pounds or more must have a tracking form.) Facilities located in nonparticipating states accepting waste from a participating state are also regulated under the program. As explained in the following pages, covered facilities must inspect packages, noting any discrepancies between the tracking form and the shipment received; sign and return tracking forms; file discrepancy reports, as necessary; and keep records.

Exceptions to the Full Tracking Program

Generally, transporters consolidate smaller shipments and prepare tracking forms to accompany them. However, in some cases facilities may accept shipments of less than 50 pounds not accompanied by a tracking form from small generators producing 50 pounds or less in a month. These shipments may be recorded in a log if

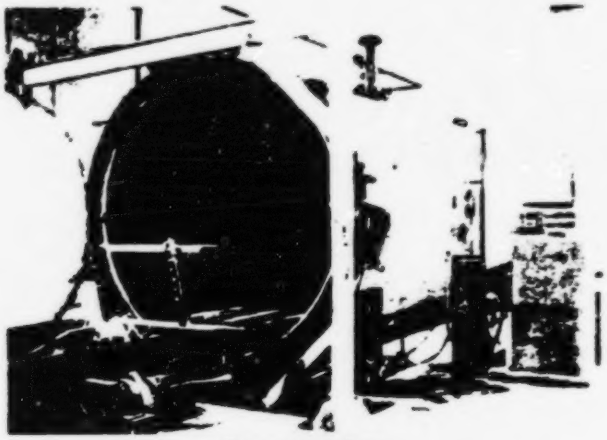
- the facility has a written agreement with the generator to accept the waste and
- the generator transports the waste in the generator's or an employee's vehicle.

For each small shipment accepted, the facility must keep records, such as a log, that include the

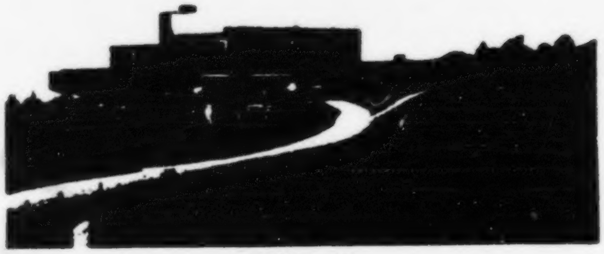
- date the waste was accepted.
- name and state permit or identification number of the generator that initiated the shipment, or the generator's address if the state does not issue numbers.
- total weight of the waste.
- signature of the person accepting the waste.

Facilities may also accept sharps sent through the U.S. Postal Service registered mail, return receipt requested.

Facilities incinerating regulated medical waste generated on site are not required to track wastes under this program. There are special requirements for on-site incinerators, however. These can be found in 40 CFR Part 259, Subpart G.



Steam autoclave



Incinerator

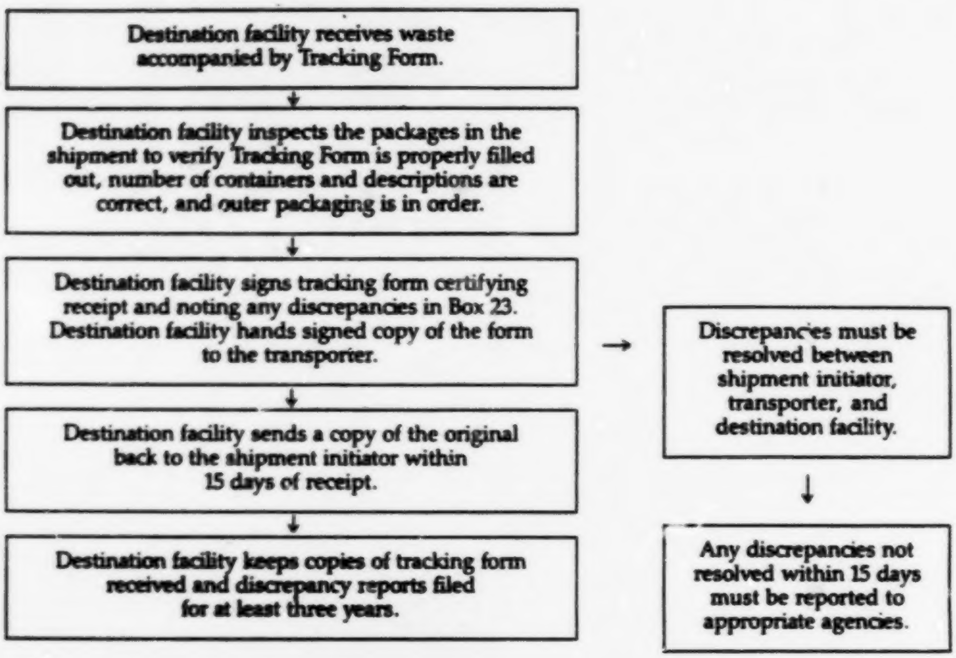
Landfill

Reproduced from
best available copy

Tracking Medical Wastes

The tracking form ensures that each shipment of waste reaches its destination. Therefore, it is crucial for a destination facility or an intermediate handler receiving a shipment of waste to sign a copy of this form, give a copy to the transporter upon accepting the waste, and follow the correct procedure for returning a copy to the generator or initiator of the tracking form. Figure 3 shows the medical waste tracking process for destination facilities; Figure 4, for intermediate handlers. Facilities receiving wastes by rail should refer to Figure 5.

FIGURE 3. Tracking Process for Destination Facility.


Destination facility receives waste accompanied by Tracking Form.
Destination facility inspects the packages in the shipment to verify Tracking Form is properly filled out, number of containers and descriptions are correct, and outer packaging is in order.
Destination facility signs tracking form certifying receipt and noting any discrepancies in Box 23. Destination facility hands signed copy of the form to the transporter.
Discrepancies must be resolved between shipment initiator, transporter, and destination facility.
Destination facility sends a copy of the original back to the shipment initiator within 15 days of receipt.
Destination facility keeps copies of tracking form received and discrepancy reports filed for at least three years.
Any discrepancies not resolved within 15 days must be reported to appropriate agencies.

Intermediate Handler Special Rules

When an intermediate handler accepts regulated medical waste with a tracking form, the handler must first check the shipment, note any discrepancies, sign, and give a signed copy of the form to the transporter. Since the intermediate handler does not both treat and destroy or dispose of waste, the handler is required to continue tracking the waste to a destination facility for final disposal.

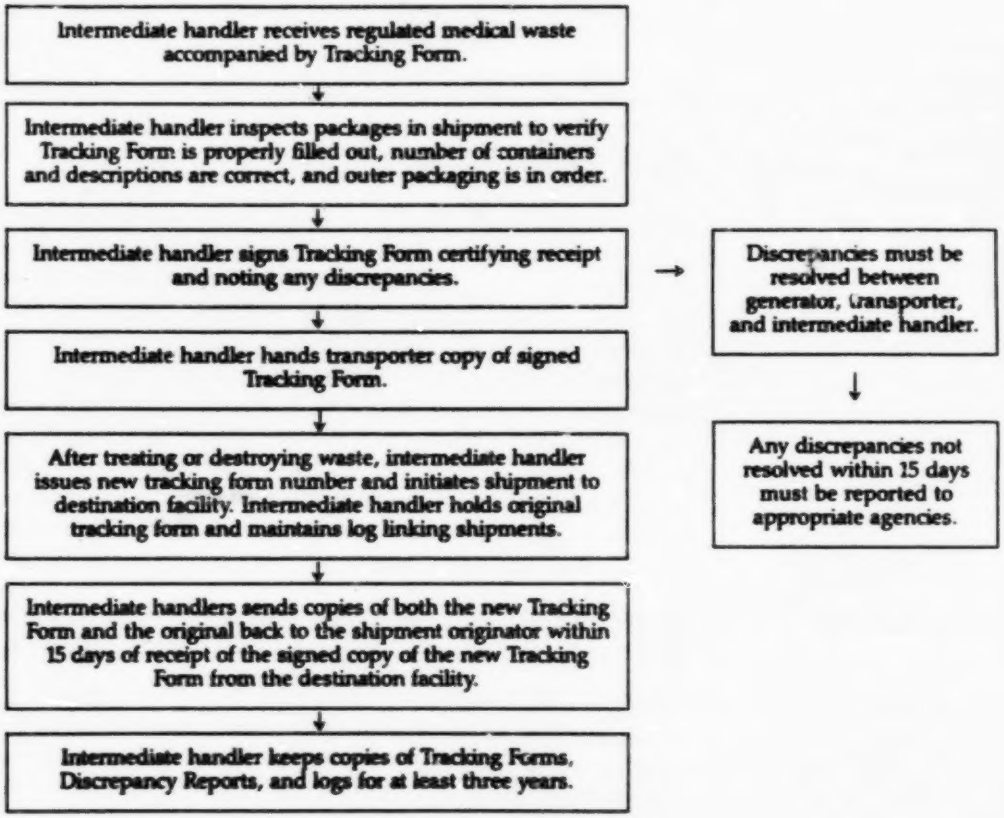
After treating or destroying the waste, the intermediate handler must initiate a new tracking form to indicate any changes in the number, weight, or contents of the processed waste, and the handler must enter a new tracking form number in Box 21 of the original form (see Figure 1) as a link between the new waste shipment and the one received for processing. In addition, the handler must assume the role of a generator, meeting all the pre-transporting and generator rules (refer to *Managing and Tracking Medical Wastes: A Guide to the Federal Program for Generators*).

Furthermore, the intermediate handler must maintain a log that further links the information on the new tracking form with that on the original tracking form. The log must include the

- name of generator.
- generator's state permit or identification number, or address if the state does not issue a permit or identification number.
- date of the original shipment or generator's tracking form number.
- new tracking form number.

When the intermediate handler receives the signed and returned new tracking form from the destination facility acknowledging receipt of the waste for disposal, the handler attaches this new form to a copy of the original form and sends both to the original generator. These forms are to be sent within 15 days to assure the original generator that the waste was received at the destination facility and that no exception reporting is needed. (The generator is required to file an exception report if the original form is not returned within 45 days.)

FIGURE 4. Tracking Process for Intermediate Handler.



Intermediate handler receives regulated medical waste accompanied by Tracking Form.

Intermediate handler inspects packages in shipment to verify Tracking Form is properly filled out, number of containers and descriptions are correct, and outer packaging is in order.

Intermediate handler signs Tracking Form certifying receipt and noting any discrepancies.

Intermediate handler hands transporter copy of signed Tracking Form.

After treating or destroying waste, intermediate handler issues new tracking form number and initiates shipment to destination facility. Intermediate handler holds original tracking form and maintains log linking shipments.

Intermediate handlers sends copies of both the new Tracking Form and the original back to the shipment originator within 15 days of receipt of the signed copy of the new Tracking Form from the destination facility.

Intermediate handler keeps copies of Tracking Forms, Discrepancy Reports, and logs for at least three years.

Discrepancies must be resolved between generator, transporter, and intermediate handler.

Any discrepancies not resolved within 15 days must be reported to appropriate agencies.

Figure 5. Receiving Medical Wastes by Rail

A destination facility or an intermediate handler may accept medical wastes shipped by rail. These wastes are to be accompanied by a tracking form or, in some cases, by shipping papers containing all information required on the tracking form, except signatures. If no tracking form comes with the waste, the facility owner or operator should expect to receive it by mail or other means from the last non-rail transporter. In any case, the owner or operator upon receipt of the rail shipment

- checks the shipment and notes discrepancies, if any.
- signs and dates each copy of the tracking form or, if no tracking form has been received, shipping papers.
- gives a copy of the signed tracking form, or shipping papers, immediately to the rail transporter.
- sends (if a destination facility) a copy of the signed and dated form within 15 days to the generator or the initiator of the tracking form. If the tracking form has not been received within 15 days, the destination facility sends a signed and dated copy of the shipping papers to the shipment initiator.
- holds (if an intermediate handler) a copy of the tracking form or shipping papers. When the handler receives a signed new tracking form from the destination facility indicating that the waste was received, the handler sends copies of both the new and original tracking forms to the generator or initiator of the original form (or shipping papers).

Tracking Form Discrepancies

In some cases, a tracking form may indicate differences between what is received and what is noted on the form or shipping papers. For example, the actual number of containers or the categories of waste may not be consistent with the information on the form, the packaging may be leaking, or the tracking form may be missing or incomplete. If such significant discrepancies occur, the owner or operator of a destination facility or an intermediate handler must try to resolve the problem. If the discrepancy cannot be resolved, it must be reported in writing within 15 days to the EPA Regional Administrator for both the generator and the facility states, and to the generator state agency. The letter is to describe the problem and any attempts to solve it; a legible copy of the tracking form or shipping papers is to be attached. If a tracking form is required to accompany the waste but is missing or incomplete, the report is to specify the quantity of waste received and identify the generator and transporter.

Keeping Records

Facility owners or operators receiving regulated medical waste are to maintain records for three years after accepting the waste. The following information must be on file:

- copies of all tracking and shipping forms and logs.
- name and state identification or permit number of each generator that delivered waste directly to the facility, or the generator's address if the state does not issue numbers; the total weight accepted; and the date the waste was accepted.
- copies of all discrepancy reports.

Other Reports

Owners and operators may be required to provide reports to EPA concerning how much medical waste was received and what treatment and disposal methods were applied.

Medical Waste Facility Checklist

If you represent a facility receiving medical waste regulated under this program, the following list is designed to help you comply with the program requirements.

________ Facility (owner or operator) is located in a participating or nonparticipating state and receives regulated medical waste generated in a participating state. (If yes, continue.)

________ Facility accepts shipment of 50 pounds or less of sharps through U.S. Postal Service. (If yes, sign mail receipt.)

________ Facility accepts shipments of 50 pounds or less from generator that has a contract and delivers waste in generator vehicle. (If yes, maintain facility log for three years.)

________ Facility accepts regulated medical waste accompanied by a tracking form or shipping papers. (If yes, continue.)

________ Facility owner or operator examines tracking form to see that it is filled out and signed by both the generator (Box 15) and transporter (Box 16), and if applicable, the intermediate handler (Box 20). (Continue.)

________ Facility owner or operator examines the shipment and notes any discrepancies (Box 23) between the tracking form and the shipment, such as piece count. (Continue.)

________ Facility owner or operator signs tracking form or shipping papers.

________ Facility owner/operator hands copy to transporter.

________ Discrepancies are investigated and, if not resolved within 15 days, letter sent to EPA Regional Administrator(s) for generator and facility state(s), and generator state agencies.

If Facility is a Destination Facility

________ Destination facility sends copy of tracking form or shipping papers back to tracking form initiator.

________ Copies of tracking forms, receipts, shipping papers, logs, and discrepancy reports are retained in facility records for three years.

Or If Facility is an Intermediate Handler

________ Intermediate handler issues a new tracking form number in Box 21, initiates a new tracking form to accompany waste to destination facility, and maintains log.

________ Intermediate handler, within 15 days of receipt of signed and returned form from destination facility, attaches original form to new tracking form and sends both copies to generator or initiator of original form.

________ Copies of tracking forms, receipts, shipping papers, logs, and discrepancy reports are retained in facility records for three years.

Glossary

Following are the classes of regulated medical wastes and a description of each.

Cultures and Stocks	Cultures and stocks of infectious agents and associated biologicals including: cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.
Pathological Wastes	Human pathological wastes, including tissues, organs, and body parts and body fluids that are removed during surgery or autopsy or other medical procedures, and specimens of body fluids and their containers.
Human Blood and Blood Products	Liquid waste human blood; products of blood; items saturated and/or dripping with human blood; or items that were saturated and/or dripping with human blood that are now caked with dried human blood including serum, plasma, and other blood components, and their containers, which were used or intended for use in either patient care, testing and laboratory analysis, or the development of pharmaceuticals. Intravenous bags are also included in this category.
Sharps	Sharps that have been used in animal or human patient care or treatment or in medical, research, or industrial laboratories. These include hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.
Animal Waste	Contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals, or testing of pharmaceuticals.
Isolation Wastes	Biological waste and discarded materials contaminated with blood, excretion, exudates, or secretions from humans who are isolated to protect others from certain highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.
Unused Sharps	The following unused, discarded sharps: hypodermic needles, suture needles, syringes, and scalpel blades.

The following terms are defined here to address the management of medical wastes. They may be different from those federal definitions used for solid or hazardous waste.

Biologicals	Preparations made from living organisms and their products, including vaccines, cultures, etc. intended for use in diagnosing, immunizing, or treating humans or animals, or in related research.
Blood Products	Any product derived from human blood, including but not limited to blood plasma, platelets, red or white blood corpuscles, and other derived licensed products, such as interferon.
Body Fluids	Liquid emanating or derived from humans and limited to blood; cerebrospinal, synovial, pleural, peritoneal, and pericardial fluids; and semen and vaginal secretions.
Central Collection Point	A location where a generator consolidates regulated medical waste brought together from original generation points prior to its transport off-site or its treatment on-site.
Container	Any portable device in which a material is stored, transported, disposed of, or otherwise handled. The term container, when describing the packaging requirements, does not include items that are regulated medical waste.
Decontamination	The process of reducing or eliminating the presence of harmful substances, such as infectious agents, so as to reduce the likelihood of disease transmission from those substances.
Destination Facility	The disposal facility, the incineration facility, or the facility that both treats and destroys regulated medical waste to which medical wastes are shipped.
Destroyed Regulated Medical Waste	Regulated medical waste that has been ruined, torn apart, or mutilated through processes such as thermal treatment, melting, shredding, grinding, tearing, or breaking, so that it is no longer generally recognizable as medical waste, but has not yet been treated. It does not mean compacted regulated medical waste.

estruction Facility	A facility that destroys regulated medical waste by ruining or mutilating it, or tearing it apart.
acility	All contiguous land and structures, other appurtenances, and improvements on the land used for treating, destroying, storing, or disposing of regulated medical waste. A facility may consist of several treatment, destruction, storage, or disposal operational units.
enerator	Any person, by site, whose act or process produces regulated medical waste or whose act first causes a regulated medical waste to become subject to regulation. In the case where more than one person (e.g., doctors with separate medical practices) is located in the same building, each individual business entity is a separate generator. [Note: see definition of "person."]
nfectious Agent	Any organism (such as a virus or a bacteria) that is capable of being communicated by invasion and multiplication in body tissues and capable of causing disease or adverse health impacts in humans.
ntermediate Handler	A facility that either treats regulated medical waste or destroys regulated medical waste but does not do both. The term does not include transporters.
aboratory	Any research, analytical, or clinical facility that performs health care-related analysis or service. This includes medical, pathological, pharmaceutical, and other research, commercial, or industrial laboratories.
andfill	A disposal facility or part of a facility where regulated medical waste is placed in or on the land and which is not a land treatment facility, a surface impoundment, or an injection well.
edical Waste	Any solid waste which is generated in the diagnosis, treatment (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. The term does not include any hazardous waste identified or listed under 40 CFR Part 261 or any household waste as defined in 40 CFR §261.4(b)(1).
n-site	The same or geographically contiguous property which may be divided by public or private right of way, provided the entrance and exit between the properties is at a crossroads intersection, and access is by crossing as opposed to going along the right of way. Non-contiguous properties owned by the same person but connected by a right of way which he controls and to which the public does not have access is also considered on-site property.
riginal Generation Point	Location where regulated medical waste first becomes waste (is "generated").
versized Regulated Medical Waste	Medical waste that is too large to be placed in plastic bags or standard containers.
Package or Outside Package	The packaging/container and its contents.
Packaging	The assembly of one or more containers and any other components necessary to assure minimum compliance with the program's packaging requirements.
Person	An individual, trust, firm, joint stock company, corporation (including a government corporation), partnership, association, state, municipality, commission, political subdivision of a state, any interstate body, or any department, agency or instrumentality of the United States.
Storage	The temporary holding of regulated medical wastes at a designated accumulation area before treatment, disposal, or transport to another location.
Transfer Facility	Any transportation-related facility including loading docks, parking areas, storage areas and other similar areas where shipments of regulated medical waste are held during the course of transportation. Also, a location in which medical waste is transferred between two vehicles.
Treated Regulated Medical Waste	Regulated medical waste that has been treated to substantially reduce or eliminate its potential for causing disease, but that has not yet been destroyed.
Treatment	When used to refer to waste handling, it means any method, technique, or process designed to change the biological character or composition of any regulated medical waste so as to substantially reduce or eliminate its potential for causing disease.

Appendix

EPA Regional Offices

Region I
State Waste Programs Branch
JFK Federal Building
Boston, MA 02203
(617) 573-5758

Region II
Air and Waste Management Division
26 Federal Plaza
New York, NY 10278
(212) 264-5166

Caribbean Field Office
(809) 729-6920

Region III
Waste Management Branch
841 Chestnut Building
Philadelphia, PA 19107
(215) 597-2842

Region IV
Hazardous Waste Management Division
345 Courtland Street, N.E.
Atlanta, GA 30365
(404) 347-3016

Region V
RCRA Activities
230 S. Dearborn Street
Chicago, IL 60604
(312) 353-9510

Region VI
Air and Hazardous Materials Division
1445 Ross Avenue
Suite 1200
Dallas, TX 75270
(214) 655-6652

Region VII
RCRA Branch
726 Minnesota Avenue
Kansas City, KS 66101
(913) 236-2856

Region VIII
Waste Management Division
999 18th Street, Suite 500
Denver, CO 80202
(303) 293-1496

Region IX
Toxics and Waste Management
215 Fremont Street
San Francisco, CA 94105
(415) 974-8388

Region X
Waste Management Branch
1200 Sixth Avenue
Seattle, WA 98101
(206) 442-6501

APPENDIX 4

Home Health Care Disposal Tip Pamphlet

APPENDIX 5

PROPOSED MEDICAL WASTES GRANTS

STATE	PURPOSE	$ AMOUNT-5% matching
Louisiana	Training: To address the needs of sanitary landfills and/or MWI operators, and to develop a training program for LDEQ's field inspectors. Approved: Complements on-going educational efforts by targeting specific audiences that may not have been adequately addressed during previous training sessions attended by EPA.	34,000
Washington	Home Health Education and Awareness: To educate the public on proper disposal of home generated infectious waste, and to differentiate between real and perceived risks. Approved: Complements on-going educational efforts by addressing fact vs. fiction risk issues concerning MW generated in the home.	57,000
California	Development of New Medical Waste Disposal Technical: To improve and develop an approval process of new medical waste disposal technologies. Approved: Complements on-going research activities that involve certification requirements for new treatment technologies.	108,500

STATE	PURPOSE	$ AMOUNT-5% matching
Connecticut	MW Tracking: Use of electronic reporting and recordkeeping without hard copy requirements. Approved: Complements on-going activities by possibly offering a standardized recordkeeping system at the national label. This project goes beyond what we would expect covered States to do with operating grants.	76,000
Michigan	Waste Composition/Volume Study: Develop operational data on medical wastestreams generated in Michigan. Approved: Data from study may be nationally applicable. Existing data gathering efforts being conducted by OSW to determine generation rates and volume amounts.	125,000

NOTE: Four additional states' proposals received preliminary approval. These states declined to submit formal grant applications.

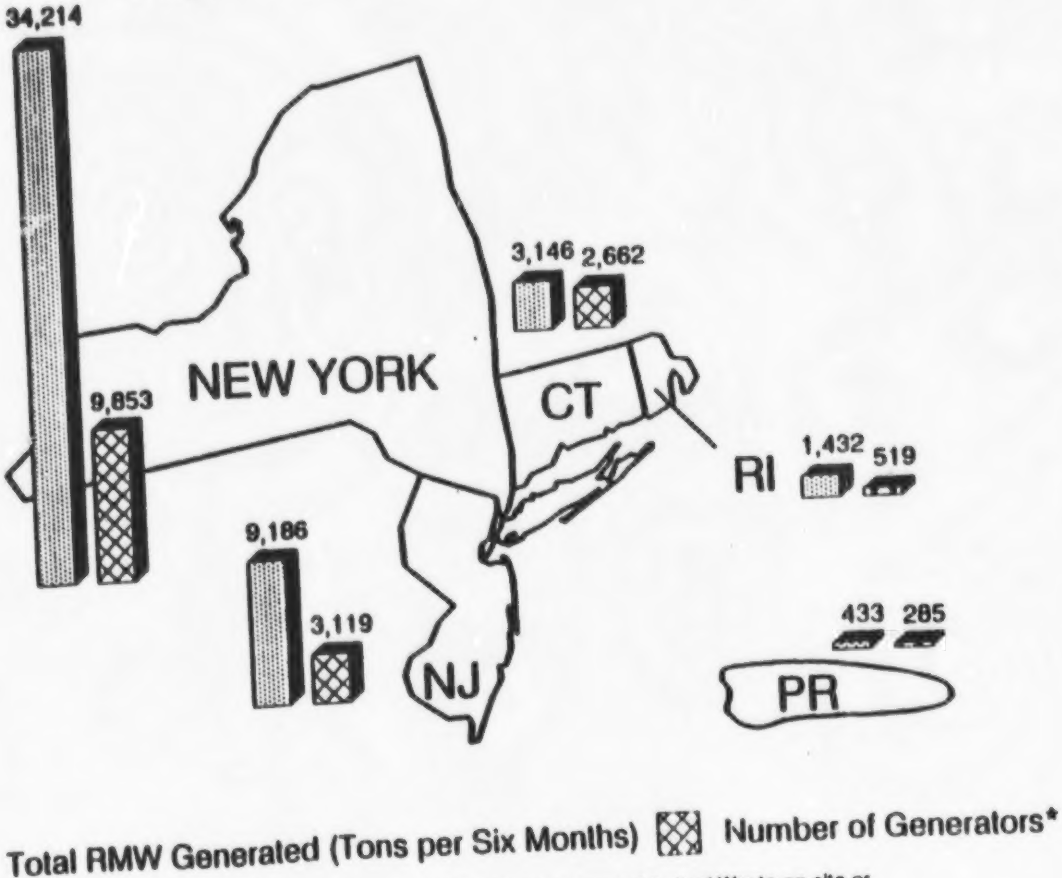
The remaining funds appropriated for State implementation of the demonstration program were distributed to the Covered States through the EPA Regional Offices.

APPENDIX 6

Information Charts and Materials from the First Reporting Period

Figure 1

Number of Regulated Generators and Quantity (Tons per Six Months) of Regulated Medical Waste Generated by Covered State



* Includes generators operating that either incinerate Medical Waste on-site or ship Medical Waste off-site using a transporter that has notified EPA.

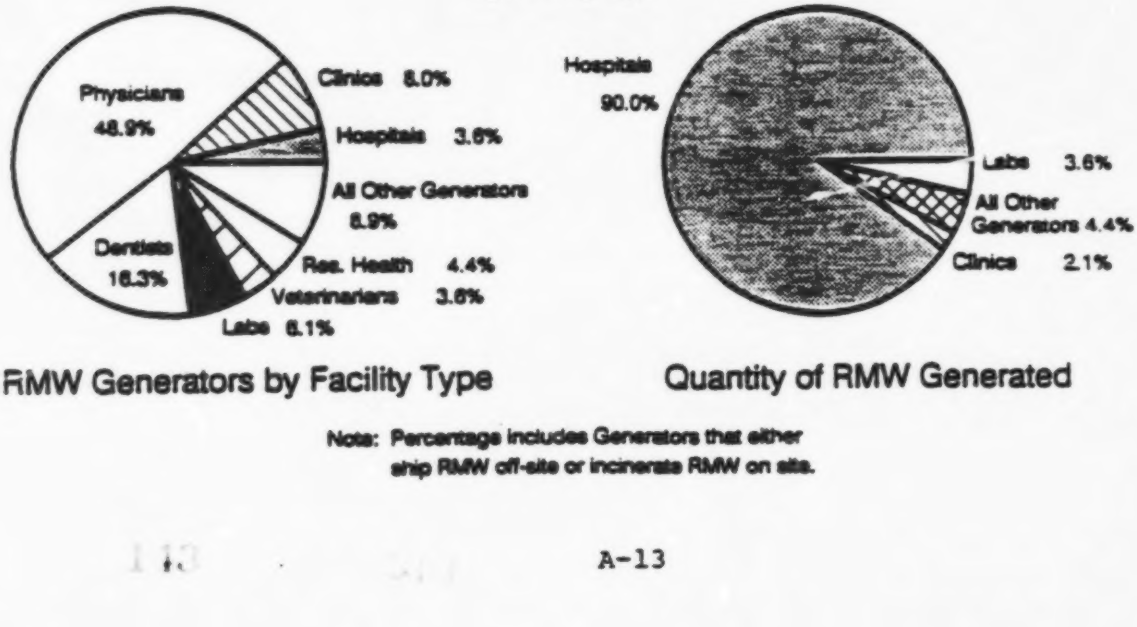
Figure 2

Total Number of Medical Waste Generators and Quantity of Medical Waste Generated by Generator Type

Type of Generator	Number of Generators	Quantity of RMW Generated (Tons/6 mo.)	Percent that Generate <50 lbs/mo.
Hospitals	599	43,557	9
Laboratories	997	1,747	63
Clinics	1,320	993	72
Physicians	8,045	384	95
Dentists	2,684	75	98
Veterinarians	597	32	95
Long Term Health	725	528	59
Blood Banks	22	167	0
Other	1,449	928	85
Total	16,438	48,411	86

Figure 3

Regulated Medical Waste Generators by Facility Type



RMW Generators by Facility Type

Quantity of RMW Generated

Note: Percentage includes Generators that either ship RMW off-site or incinerate RMW on site.

Figure 4
Number of Treatment and Disposal Facilities by Type of Management Method

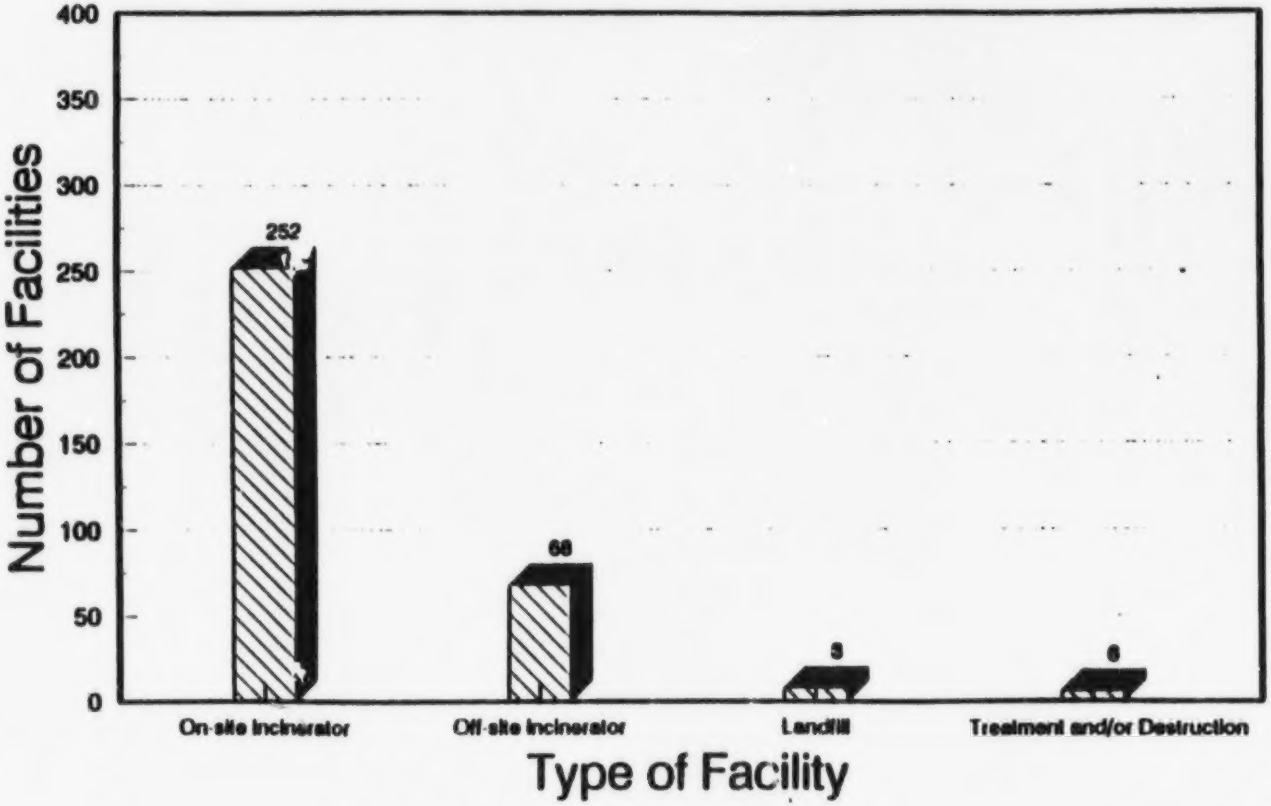


Figure 5

Quantity of Regulated Medical Waste (tons/six months) Treated and Disposed by Destination

	Destination	Medical Waste Incinerated On-site (tons)	Medical Waste Transported Off-Site (tons): Incinerator	Medical Waste Transported Off-Site (tons): Landfill	Medical Waste Transported Off-Site (tons): Treatment and/or Destruction	Total (tons): Treated & Disposed
Covered States	Connecticut	420	1,799	87		2,306
	New Jersey	4,813	509			5,322
	New York	12,410	1,163	181	21.4	13,775
	Puerto Rico	95	275	18		388
	Rhode Island	859	1,038			1,897
Non-Covered States	Arkansas	*	2,573			2,573
	Florida	*	382			382
	Indiana	*			0.11	<1
	Massachusetts	*	163			163
	Maryland	*	186			186
	North Carolina	*	1,343			1,343
	North Dakota	*	4,132			4,132
	Ohio	*	1,759		225	1,984
	Pennsylvania	*	851		496	1,347
	South Carolina	*	7,908			7,908
	Virginia	*	3,473			3,473
	Canada	*	1,053			1,053
	Total:	18,597	28,607	286	743	48,233

* = This column only pertains to regulated medical waste incinerated on-site by generators in the Covered States. Therefore, non-Covered States would not display any quantities in this column.

Figure 6

Total Quantity of Regulated Medical Waste Generated (tons/six months) and Percentage of Waste Exported Out-of-State for Treatment or Disposal

Covered States	Quantity of RMW Generated	Percent Transported Out-of-State for Treatment and Disposal
Connecticut	3,146	35
New Jersey	9,188	47
New York	34,214	59
Puerto Rico	433	0
Rhode Island	1,432	20

United States
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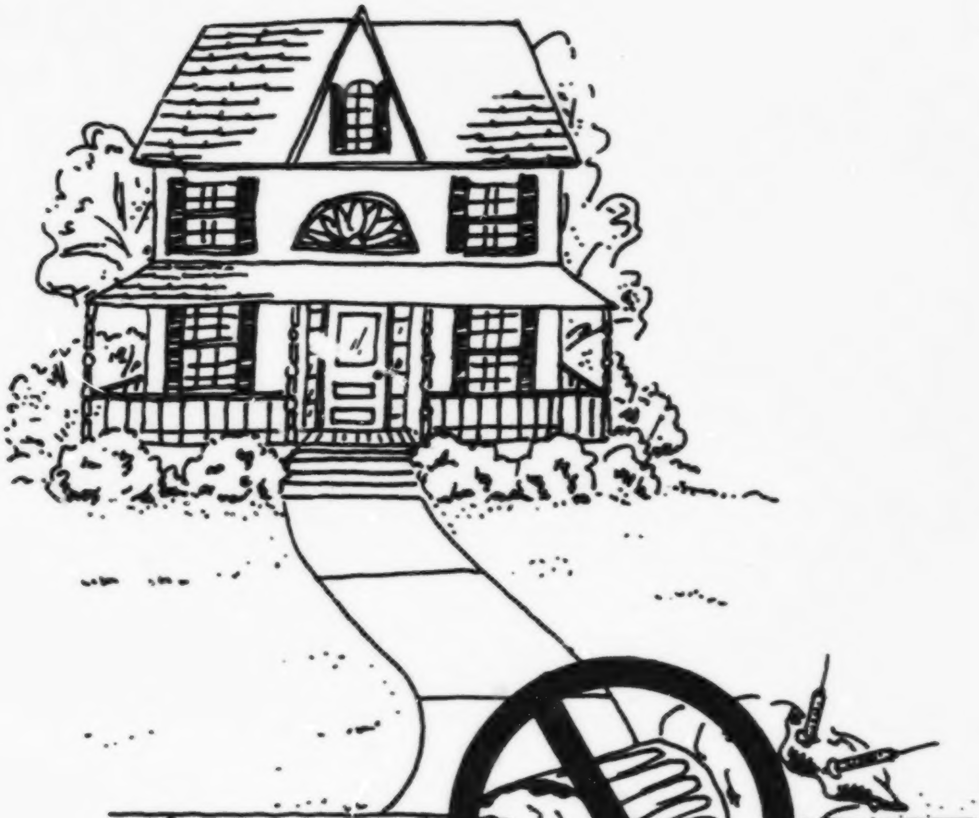
January 1990

Solid Waste and Emergency Response (OS-305)

EPA

Disposal Tips for Home Health Care



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Educating Your Patients

Millions of households produce medical wastes

Every year, Americans use over one billion sharp objects in their homes to administer health care. These "sharps" include lancets, needles, and syringes. If they are not disposed of in puncture-resistant containers, they can injure trash handlers; can increase the risk of infection if they come in contact with contaminated materials such as bandages, dressings, and surgical gloves; and can pollute the environment.

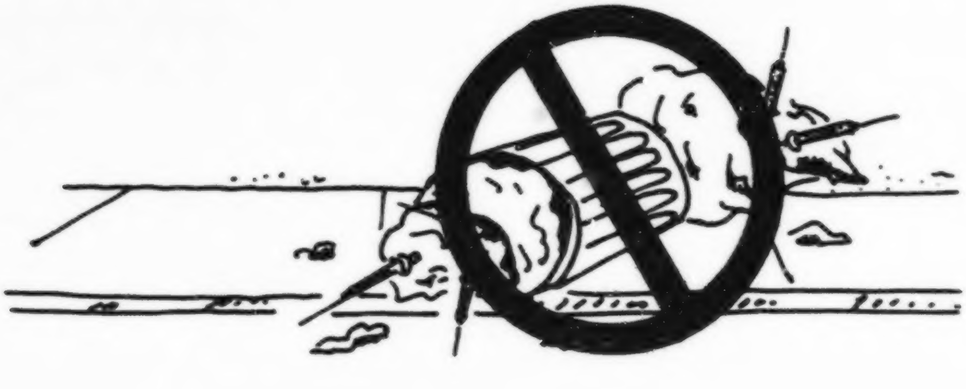
We need your help in educating them

As a health-care professional, you play an important role in instructing your patients and clients on how to safely practice health care at home. Through this brochure, we are asking your help in distributing the attached disposal tips to them. The tear-out explains how to safely dispose of sharps and other contaminated medical waste, such as bandages and soiled disposable sheets.

Please distribute the attached tear-out to your patients

We urge you to distribute the disposal tips tear-out to your patients and to encourage them to read it. You might also place this information in areas easily accessible to all your patients and clients.

You can get additional free copies of this brochure or reprints of the tear-out by sending the attached order form to EPA. For further information on medical waste, you can call the RCRA Hotline Monday through Friday, 8:30 a.m. to 7:30 p.m. EST. The national toll-free number is (800) 424-9346; for the hearing impaired, it is TDD (800) 553-7672. In Washington, DC, the number is (202) 382-3000 or TDD (202) 475-9652.



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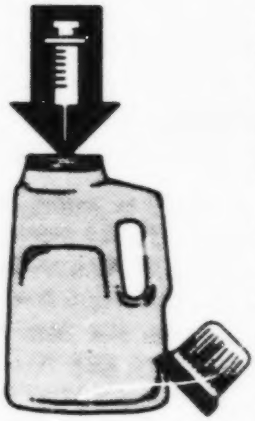

You can help prevent injury, illness, and pollution by following some simple steps when you dispose of the sharp objects and contaminated materials you use in administering health care in your home. You should place:

- **Needles,**
- **Syringes,**
- **Lancets, and**
- **Other sharp objects**

in a hard-plastic or metal container with a screw-on or tightly secured lid.

A coffee can will do, but you should be sure to reinforce the plastic lid with heavy-duty tape. Do not put sharp objects in any container that will be recycled or returned to a store. Do not use glass or clear plastic containers. Finally, make sure that you keep containers with sharp objects out of the reach of young children.

We also recommend that:

- **Soiled bandages,**
- **Disposable sheets, and**
- **Medical gloves**

be placed in securely fastened plastic bags before you put them in the garbage can with your other trash.

Your state or community environmental programs may have other requirements or suggestions for disposing of your medical waste. You should contact them for any information you may need.

More Information

For additional copies of these disposal tips, please call the RCRA Hotline Monday through Friday, 8:30 a.m. to 7:30 p.m. EST. The national toll-free number is (800) 424-9346; for the hearing impaired, it is TDD (800) 553-7672. In Washington, DC, the number is (202) 382-3000 or TDD (202) 475-9652.

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